

PERSIAN GULF WAR ILLNESSES

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTH CONGRESS

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PERSIAN GULF WAR ILLNESSES

TUESDAY, FEBRUARY 11, 1997

HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The committee met, pursuant to call, at 1 p.m., in room 334, Cannon House Office Building, Hon. Bob Stump (chairman of the committee), presiding.

Present: Representatives Stump, Smith of New Jersey, Bilirakis, Everett, Quinn, Bachus, Stearns, Moran, Cooksey, Hutchinson, Chenoweth, Evans, Kennedy, Filner, Gutierrez, Bishop, Mascara, Peterson, Reyes, and Snyder.

OPENING STATEMENT OF CHAIRMAN STUMP

The CHAIRMAN. The meeting will please come to order. Let me say before we start today that we have urged all members not to take their time in offering a 5-minute opening remark. If you do have a statement you would like to make, please do so at the time you ask questions.

We'll allow that at the end of each panel. But we will abide by the 5-minute rule. We have a very, very long agenda, and I know that there's a big dinner tonight at the VFW that most people would like to attend.

Today's hearing on health concerns of Persian Gulf veterans is our 11th such hearing and far from our last on this subject. We won't get all the answers or resolve all the issues today, but we will follow these issues wherever it takes us. If additional legislation is needed, we will take it up and move it very swiftly.

This afternoon we will hear testimony from scientists, government officials, and spokesmen for our veterans' organizations. Testimony from individual veterans will also remind us of the importance of providing empathetic care, timely benefits, and ultimately, real answers.

Finding answers has been slow and elusive. Hopefully these hearings will help us understand the limitations as well as importance to these issues of scientific inquiry.

Concerns regarding Persian Gulf veterans' illnesses have sparked many theories regarding both cause and cure. We will not help our veterans, however, by substituting our own judgment for that of the experts in determining the most fruitful avenues for further research. And we must not let our frustrations regarding the search for answers overtake our responsibility for judicious decisionmaking.

In that regard, the Presidential Advisory Committee on Gulf War veterans' illnesses has accomplished important work, as has the Institute of Medicine. I hope the work of these expert panels will help us agree on where we go from here.

At this time I'm happy to recognize the ranking member, Lane Evans.

OPENING STATEMENT OF HON. LANE EVANS

Mr. EVANS. Thank you, Mr. Chairman. I appreciate you holding the hearing today. We have some important witnesses before us. So I'll keep my remarks very short.

I commend President Clinton for establishing the advisory committee and its members and staff for all the important services they have provided to our country. By all accounts, their work has been thorough, competent, effective, and candid. I hope future government advisory committees will conduct the people's business in the same manner in carrying out their mandate as well.

Mr. Chairman, I anticipate some members of the Committee may have additional questions for some of the witnesses following the conclusion of this hearing. I request all members be given the opportunity to submit questions in writing to witnesses and those questions and their responses to them would be included in today's hearing record.

The CHAIRMAN. Without objection and also encouraged.

Mr. EVANS. I appreciate your holding the hearing, Mr. Chairman. Thank you.

The CHAIRMAN. Thank you, Lane.

Our first panel today will be Major Marguerite Knox, a member of the Presidential Advisory Committee on Gulf War Illnesses who also served during the Gulf War; and Dr. Russell, a member of the Institute of Medicine Committee which reviewed these issues. Major Knox, if you'd like to lead off?

And let me say to the members we are not discriminating against the members. We'd also ask the witnesses to try to hold their remarks to 5 minutes, please, each, if you would. Ms. Knox.

Ms. KNOX. Good afternoon. How are you all?

STATEMENTS OF MAJ. MARGUERITE KNOX, PRESIDENTIAL ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES, ACCOMPANIED BY HOLLY L. GWIN, DEPUTY DIRECTOR/COUNSEL, AND MARK A. BROWN, PH.D., SENIOR POLICY ANALYST; AND DR. PHILIP K. RUSSELL, PROFESSOR OF INTERNATIONAL HEALTH, SCHOOL OF HYGIENE AND PUBLIC HEALTH, JOHNS HOPKINS UNIVERSITY, AND MEMBER, PRESIDENTIAL ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES

STATEMENT OF MARGUERITE KNOX

Ms. KNOX. Mr. Chairman, members of the Committee, thank you for this opportunity to appear before you today. We have submitted written testimony for the record. As you requested, I will now summarize this material.

First, there should be no question that the Presidential Advisory Committee on Gulf War Veterans' Illnesses recognizes that many

veterans are experiencing medical problems connected to their service in the Gulf.

In the near term, the Government needs to fine-tune some specific efforts in follow-up clinical care and risk communication. Overall, the advisory committee found that the Government had learned some lessons from our experience with Vietnam in responding to the range of health-related problems experienced by Gulf War veterans.

Regarding research, the committee found that the current research portfolio is for the most part appropriately balanced. Clearly, the broad array of ongoing studies will improve our understanding of Gulf War veterans' illnesses.

To close the gaps in the current knowledge base, we recommended additional research in three specific areas: number one, on the long-term health effects of low-level exposures to chemical warfare agents; number two, on the synergistic effects of pyridostigmine bromide with other Gulf War risk factors; and, number three, on the body's physical response to stress.

In addition, the committee noted the importance of continuing to ensure that resources are devoted to mortality studies since some health effects, such as cancer, would not be expected to appear until a decade or more after the end of the Gulf War.

In reviewing the data available for our December 1996 report, the advisory committee was able to reach some conclusions about the nature of Gulf War veterans' illnesses. In this regard, we have three findings as well.

First, as I noted earlier, many veterans have illnesses connected to their service in the Gulf.

Next, the committee conducted a comprehensive review based on results subjected to peer review of the health effects of pesticides, chemical warfare agents, biological warfare agents, vaccines, pyridostigmine bromide, infectious illnesses, and depleted uranium, oil well fire/smoke, and petroleum products. Current scientific evidence does not support a causal link between the symptoms and illnesses that veterans report today and exposures to any environmental risk factor of the commonly suspected Gulf War hazards that we assessed.

And, finally, stress which is known to affect the brain, the immune system, cardiovascular system, and various hormonal responses is likely to be an important contributing factor to Gulf War veterans' illnesses.

As I just noted, prudence requires further research in this area as well as on the synergistic effects of PB and long-term health effects of low-level exposure to chemical warfare agents.

As you know, the advisory committee had one significant caveat about the Government's performance related to Gulf War veterans' health concerns. We took strong issue with the Department of Defense's efforts to assess possible exposures of U.S. troops to chemical warfare agents in the Gulf. An atmosphere of government mistrust now surrounds every aspect of Gulf War veterans' illnesses because of DOD's mishandling of this issue. This atmosphere of mistrust is regrettable.

Our investigation of DOD's efforts in this area led us to conclude the department's early efforts were superficial and lacked credibil-

ity. We found substantial evidence of site-specific low-level exposures to chemical warfare agents. Moreover, we found DOD's investigations had been superficial and were unlikely to provide credible answers to veteran's and public's questions.

The advisory committee also noted that DOD's failure to seriously investigate these issues also adversely affected decisions related to funding research and to possible health effects of low-level exposures to chemical warfare agents. DOD's intransigence in refusing to fund such research until late last year has done veterans and the public a disservice.

Before concluding my oral remarks, I do want to mention that during the course of the advisory committee's deliberations on Gulf War veterans' illnesses, we judged that the Government could do a better job in the future of avoiding post-conflict health concerns. Thus, we made several recommendations to address the need for better communication, better data collection, and better services.

I would be happy to discuss these recommendations in greater detail should you have questions, but I especially want to note a strong need to improve data collection and handling. The Government has a significant amount of ground to recover with Gulf War veterans and the American public because they have come to question whether a lack of data—for example, on the possible exposures, on the pre- and post-deployment health of veterans, or on the location of troops in theatre—actually indicates a lack of commitment to veterans' health.

Mr. Chairman and members of the Committee, the Nation has just begun to pay its debt to Gulf War veterans in many important ways. It is essential now to move swiftly toward resolving their principal remaining concerns.

Thank you again for the opportunity to review the committee's work with you. I or committee staff members Holly Gwin or Mark Brown would be happy to answer questions about our work.

On a personal note, however, I would like to add that I hope DOD and VA will respond quickly and compassionately and sincerely in providing the state-of-the-art health care that any veteran seeks in any institution within DOD and VA. Veterans need timely health care and timely receipt of benefits and compensation. I am pleased that the President supported Secretary Brown's reexamination of the presumptive period for undiagnosed illnesses. And I hope this review will be completed as soon as possible.

Finally, to quote fellow committee member Dr. Philip Landrigan in his recent editorial in the *Journal of American Medical Association*, he states, "Despite the limitations of current epidemiological studies and clinical investigations and regardless of the unanswered questions surrounding the hazards of potential exposures during the Persian Gulf War, these veterans will need all the resources and all of the care that they are owed by this Nation that they have so generously and gallantly served."

Thank you. We'll be glad to address any questions.

[The prepared statement of Major Knox appears on p. 316.]

The CHAIRMAN. Thank you, Major Knox.

Now we'll hear from Dr. Russell, who was a committee member on the committee to review the health consequence of service dur-

ing the Persian Gulf War for the Institute of Medicine. Is that correct, Doctor?

STATEMENT OF DR. PHILIP K. RUSSELL

Dr. RUSSELL. Mr. Chairman, members of the Committee, thank you for the opportunity to discuss some aspects of the health problems faced by veterans of Desert Shield and Desert Storm. I'm here in place of Dr. John Bailer, the chair of the IOM Committee to review the health consequences of service during the Persian Gulf War.

Dr. Bailer's formal statement has been submitted earlier, and I fully support his statement and am very happy to speak on behalf of the committee and answer questions about the statement.

The charge to our committee was to assess the actions taken by the Secretary of Veterans Affairs and the Secretary of Defense to collect and maintain information and generate databases useful for addressing the health consequences of service in the Gulf.

Another charge was to recommend means to improve collection and maintenance of relevant information and to determine whether there is a sound basis for epidemiologic studies of the health consequences of service in the Gulf and make recommendations regarding the studies.

Our committee met 16 times over a period of 3 years and received information from a wide variety of sources, including veterans, physicians, epidemiologists, research scientists, and military experts.

Forty-five recommendations from our committee are contained in the two published reports. Our recommendations emphasize the urgent need for improved medical record systems and compatible medical databases in the armed services and the Department of Veterans Affairs.

We made a series of recommendations directed at improving ongoing research programs, and we emphasized the need for additional efforts in several areas, including stress management in military operations, stress-related disorders, excess accident mortality in veterans, and longitudinal studies of veterans' health and causes of morbidity and mortality.

We made several recommendations aimed at improving the capability of the armed forces to relate experiences and potential environmental exposures during deployment to medical outcomes.

We supported the continuation of ongoing epidemiologic and toxicologic research, including studies of the long-term effects of chemical warfare agents.

In the course of our studies, we reviewed information in 14 different hypotheses, which have been put forward as possible explanations for illnesses in veterans of the Gulf War or causes of the Gulf War Syndrome.

We found no convincing evidence to support any of the proposed explanations. Our committee found no convincing evidence for a definable or unique new medical condition among Gulf War veterans and no direct evidence for environmental exposures causing adverse physical or physiologic consequences.

More recent information regarding potential exposures to chemical weapons from destruction of captured munitions raises ques-

tions about documenting exposure and defines a population deserving further study. However, it does not alter our conclusions or recommendations. Our conclusions and recommendations were based on an assumption that low-level exposure was a possibility that had not been excluded and may never be adequately determined.

The Presidential Advisory Committee on Gulf War Illnesses addressed several of the same issues as the Institute of Medicine committee. In those areas, there's almost complete agreement. Differences are really very minor and a matter of emphasis and perspective, matter of tone.

Both committees recognized the profound impact that service in the Gulf War had on the health of the deployed military population. Although battle injuries and infectious disease casualties were low, stress-related illnesses and ill-defined symptoms and symptom complexes has created a serious disease burden.

Access to care problems and adverse determinations regarding service-connected illnesses created serious social and medical consequences as well as confounding early epidemiologic consequences.

Both committees as well as earlier groups which addressed the problem came to the same conclusion regarding the lack of convincing evidence for a causative role for the suspected environmental toxins, oil fire/smoke, petroleum products, depleted uranium, chemical and biologic weapons, vaccines, medications, repellents, and insecticides.

In closing, let me say that I have become very doubtful that after almost 6 years of intense study, investigation, and debate, we will ever come to a conclusion about the existence of Gulf War Syndrome or that we will ever find convincing evidence of long-term health effects resulting from exposure to a specific causative agent or combination of agents. There are still very important areas for additional study and research, but I have very little optimism that we will find definitive answers or agree on the answers.

The most important actions in my view are in the areas of assuring optimal medical care and support for this group of veterans and for veterans of future conflicts. We should give high priority to developing epidemiologically sound medical record systems and accurate deployment records. We should strengthen the capability of the armed forces to rapidly and thoroughly investigate all medical problems related to future deployment.

Thank you very much for the opportunity to be here.

[The statement of Dr. John Bailer appears on p. 322.]

The CHAIRMAN. Thank you, Doctor.

I have one quick question of either of you or maybe both. A report suggesting that Persian Gulf veterans' family members have been getting sick and that their offspring have had birth defects has been alarming. Does the available research offer any reassurance on this? Would either of you care to?

Dr. RUSSELL. The studies that were available to our committee were in early stages of their producing results, but the data that we saw did not indicate any excess problems of birth defects within the population. There are ongoing studies that will continue to address this.

The CHAIRMAN. Thank you.

Ms. KNOX. Our conclusion was essentially the same about both of those.

The CHAIRMAN. Thank you, Mr. Evans.

Mr. EVANS. Thank you, Mr. Chairman.

I'd like to ask the panel about stress. Stress has been cited repeatedly as a possible factor in the continuing health problems of our Persian Gulf veterans. Is stress considered a leading cause because knowledge of other possible causes is lacking?

Ms. KNOX. I don't think that's so at all. I think that stress is definitely a contributing factor to anybody who participates in war. And, having been there, it's a very stressful environment. Just like we know that many people have hypertension due to stress-related complications in their lives, stress can cause, may not be the only cause, but it's a contributing factor to certain disease processes.

Do you want to add something?

Dr. RUSSELL. Stress casualties are an expected outcome of war. They have been since we have been keeping medical records of casualties during wartime.

The Gulf War was a very stressful war, and it wasn't a short war for most of the deployed troops. They were there for many months. The stress levels were very high on a continuous basis. And it was expected that we would have stress casualties from that kind of an operation. Management of stress is a continued, ongoing problem for military leadership and military medical support.

I think we were led to underestimate the impact of stress because the casualties due to hostile fire were low, the casualties due to infectious diseases were unexpectedly low. But the stress casualties were not mitigated.

Mr. EVANS. What could the military do to best reduce stress symptoms in the future?

Dr. RUSSELL. It's a complex problem. Some of the best ways of reducing stress are to prepare the troops for the environment and the hazards they have to face. Leadership is incredibly important. Unit cohesion is incredibly important in avoiding stress casualties. The better leadership, the better trained the organization, the lower the stress casualties.

Mr. EVANS. All right. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Lane.

The gentleman from Alabama, Mr. Everett.

Mr. EVERETT. Thank you, Mr. Chairman.

Major Knox and Dr. Russell, our veterans seem to be asking two questions, basically, "What caused me to get sick?" and "How can I be cured?" Are these two separate research areas?

Dr. RUSSELL. I would say so, yes, sir. The search for etiology may involve the toxicology, epidemiology, may involve other disciplines. Treatment of illness may involve dealing with the patients' total problems and medical management. They are two entirely different problems.

Mr. EVERETT. I notice from the testimony submitted that a lot of research is indicated. How are we going to ensure that the research and what happened do not interfere with us treating our veterans and trying to get a cure to them or can we do that? And how long are we talking about here?

Ms. KNOX. You know, it may be impossible to ever find a cure since veterans were exposed to so many different risk factors during the Gulf War. Just finding out about low-level chemical exposure is 5 years after the fact, so research has been delayed. So until that time, legislation will have to approve recommendations for veterans to get the care that they deserve in the VA.

Mr. EVERETT. I'm sorry, Major Knox. Did you want to add something else?

Ms. KNOX. I'm going to let Holly Gwin add to that.

Ms. GWIN. One thing that the committee found is that neither DOD nor VA is waiting until we know the precise cause or a particular cure for undiagnosed illness before they're treating the veterans. There are extensive clinical programs in place to diagnose and to treat veterans who complain of symptoms related to the Gulf War.

Mr. EVERETT. Dr. Russell, speaking of the 4-year delay, what loss has that caused us in the ability to find out exactly what happened?

Dr. RUSSELL. I think the problem is not the delay. It's that we've been at it for so many years and have exhausted—we've intensively investigated multiple proposed hypotheses. And each one of them proved not to have sufficient evidence to be a convincing candidate for suspect etiology.

I think also as time goes on, the ability to relate symptoms and illness to something in the remote past becomes more and more difficult from a medical and epidemiologic basis.

Mr. EVERETT. Could you say that DOD's inaction for 4 years on this and not allowing funding to go through at the level that it should have has caused any effect on it?

Dr. RUSSELL. We probably did not start early enough and vigorously enough with our epidemiologic investigations. Yes, sir.

Mr. EVERETT. Let me ask you a final question, please. Dr. Bailar's testimony raises a question of whether the frequency of diminished symptoms in some very serious diseases is higher for Gulf War veterans and their non-deployed counterparts. Have you found any evidence of an increase of such frequency?

Dr. RUSSELL. I haven't. I've reviewed the same data that Dr. Bailar has. And there is evidence of increased illnesses of several types among Gulf War veterans compared to their colleagues that did not deploy. There's evidence of increased mortality due to automobile accidents.

That still doesn't help us very much in determining exactly what the cause of these illnesses is.

Mr. EVERETT. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

The gentleman from California, Mr. Filner.

OPENING STATEMENT OF HON. BOB FILNER

Mr. FILNER. Thank you, Mr. Chairman. And thank you for holding these hearings.

I appreciate, Major Knox, your comments. I, too, was disturbed at some of the early reactions, the defensiveness of the Defense Department. I guess Defense Department doesn't mean you have to be defensive on these kinds of issues and on administration and re-

luctance to admit either error or wrongdoing or even ignorance, which is part of our condition and seemingly to focus on, "Well, since we can't pinpoint an exact cause, therefore, there is no responsibility here." I found those statements very disconcerting, as I think you indicated.

And, of course, now I think, as most of the questions preceding me I think were pointing to, that, regardless of whether we have that answer, it is our responsibility to assure that the health care is provided and also compensation to those individuals whose health problems are associated with this service.

Obviously we have to continue that research, but I don't think we should wait for all this complex science involved with this to come forward with a national responsibility toward our fighting men and women in the Persian Gulf. So I don't think they can wait any longer. We have to accept that responsibility and move forward, even if we never find a, quote, "exact" cause.

I'm still disturbed by people who seem to think that that's what this issue is all about since they can't find the one or because they can't find anybody at fault or we didn't do it on purpose. I mean, I saw General Schwartzkopf say, "Well, we didn't do it on purpose." Well, nobody ever said that that was.

Obviously that's not the issue here. The issue is we have thousands and thousands of people suffering. And we need to deal with that.

I read with some interest another study—I think it followed yours—by the University of Texas.

Ms. KNOX. Right.

Mr. FILNER. Are you familiar with that one, which seemed to—I mean, it took away some of the concentration on stress and looked at other syndromes that involved brain and nerve damage caused by exposure? Did you look at that and is that—

Ms. KNOX. You are speaking of Dr. Robert Haley's study out of Southwest Texas?

Mr. FILNER. I think so, yes.

Ms. KNOX. Yes. In fact, one of our members, Philip Landrigan, did the editorial on that particular issue. I think that was a good study that Dr. Haley did. And I think more studies need to be done to find out what the effects of low-level chemical exposure could have been.

However, his study still does not show a cause and effect relationship. He did a multivariate statistical analysis. And he actually wrote three articles in that particular journal, but it still does not show a cause and effect on low-level chemical exposure.

Did you want to add to that, Dr. Russell?

Dr. RUSSELL. Yes. I fully agree with Dr. Landrigan's analysis of those studies. They were ambitious, sophisticated. They raised questions, but they had substantial epidemiologic and methodologic weaknesses and limitations of the study population. They raised interesting and worthy questions, but they're not conclusive.

One of the conclusions that was drawn in the study was that the neurologists and the investigators who were blinded to the subject whether they were cases or controls could not differentiate on the basis of clinical laboratory findings between the cases and the con-

trols. The findings were nonspecific and not sufficient to diagnose a known syndrome or in any subgroup.

So it is useful research, but it doesn't provide us with definitive answers.

Ms. KNOX. However, we welcome further research on that area because we just don't have the answers regarding low-level chemical exposures.

Mr. FILNER. You used a few interesting words in your opening statement, including "superficial" and some other ones, which I agreed with, as I said. Has the DOD been responsive to that critique? I mean, have they accepted that or are they still trying to defend what they were doing? I mean, are they on a new path in your view that—

Ms. KNOX. I think so. I think that Secretary John White was very sincere in his last remarks to our committee. I think the biggest problem that DOD has had is in their communication. Risk communication has been very poor.

I am still employed by DOD. And I would like to think that it acts in the best interests of our veterans. And it is a big organization. So there have been problems.

Mr. FILNER. Thank you. I just hope that your findings, your statement can get us on the path of a constructive dealing with some real human problems. And honesty about what we did or didn't do I think has to be there because I don't care where the chips fall. If we have done something wrong or something stupid or something out of ignorance, we need to know it. I mean, it's in our national interest to be honest here and not to—

Ms. KNOX. I agree.

Mr. FILNER (continuing). Hide or cover up, be defensive or superficial. I mean, that's what national security to me means in the future: to be honest about what happens here. And I think your report has helped us.

Thank you.

The CHAIRMAN. The gentleman from New York, Mr. Quinn.

OPENING STATEMENT OF HON. JACK QUINN

Mr. QUINN. Thank you, Mr. Chairman. I want to thank you, Chairman, and the Ranking Member Evans for your interest in holding today's hearing. I'm looking forward to this Committee becoming more and more involved in this issue as we hear testimony today, both from this panel and other members on panels later this afternoon.

I also want to thank the commission for their work in responding to us, not only as members of the U.S. Congress, but also as we try to respond to constituents back home in our states and cities and districts all across the country.

Mr. Chairman, I have a statement that I would like included in the record for later.

The CHAIRMAN. Without objection.

[The prepared statement of Congressman Quinn follows:]

PREPARED STATEMENT OF HON. JACK QUINN

Mr. Chairman, thank you for holding this important hearing on the illnesses that are facing some of our Gulf War veterans. I congratulate the Advisory Commission on

their work and I am pleased they will continue their service to America's veterans for several more months.

Mr. Chairman, I approach this issue with an open mind on almost every aspect except the way the Department of Defense has handled the issue.

Veterans are sick. There is no doubt about that. The issue before this committee is to determine how VA is now taking care of sick veterans and what VA is doing in terms of research and how VA is compensating veterans for their service-connected disabilities.

The Commission makes several interesting recommendations regarding record keeping at DOD and VA. As Chairman of the Subcommittee on Benefits, I am very interested in VA and DOD standardizing medical and personnel records to ensure the most seamless handoff between DOD and VA possible. In addition to easing the data collection in cases like this, it will make VA's job easier in all future benefits cases.

Mr. Chairman, I am also concerned about how VA is handling compensation claims. I understand that VA is in the process of re-evaluating several thousand claims at this time to determine whether VA had processed the claims properly. I urge VA to complete the project as quickly as possible. I am also aware that Secretary Brown is considering adjusting the two year presumptive period for compensation claims. I know that he has been pressed hard by some members of the other body to take an immediate administrative active to lengthen the presumptive period and that he has stated that he needs to see the data before he takes action. I support that approach, and I am pleased that Secretary Brown will make his decision based on available data, not emotional appeal.

To determine how VA has been handling Persian Gulf compensation cases, I will schedule a hearing in the spring. That will allow time for VA to accumulate data from its re-evaluation project to give us a good picture of how veterans are being served. If necessary, I intend to hold an additional hearing this fall on the issue.

Mr. Chairman, that concludes my remarks.

Mr. QUINN. Major Knox, you talked about one of the recommendations that the committee saw fit to include was to talk about better communications. And, clearly, that's one of the things I think we have to work on with the Department of Defense, for example, when we talk about communications and asking questions and receiving straightforward answers and so on and so forth.

Can you briefly state what recommendations you make in terms of communications, between whom and with whom and how it might be helpful, or are you not able to do that at this time?

Ms. KNOX. I'll let Holly Gwin speak to that since she's deputy counsel.

Ms. GWIN. We made a number of recommendations about communication. The two most forward-looking ones have to do with—well, the first one is DOD and VA need to get together and develop a risk communication plan to explain to veterans, in advance as well as after the fact, to their best ability what are the risks that they face in a wartime situation and what are the possible health consequences of those risks.

Mr. QUINN. I understand.

Ms. GWIN. That seems to be a basic area of misunderstanding right now.

Another area where we thought there needed to be vastly improved communication is in the area of drugs, investigational drugs, that are approved for use under an interim waiver of conformed consent now available from FDA. Drugs like pyridostigmine bromide, although they're approved for one use, are not approved for the use in which they were employed during the war.

We figured there needed to be much better communication, not only to the service members about what they were taking, but a

broadier public dialogue about whether that is an appropriate use of drugs in this society.

Mr. QUINN. Thank you, Ms. Gwin. Those are both very helpful.

Would it be possible for you to sort of get for me and for the Committee other areas of communication that you looked at? For example, is there any discussion about communication between the various departments and this Committee?

Now that the event is over, we have a tough time getting some information sometimes. Is that area of communication addressed at all in the report?

Ms. GWIN. No.

Mr. QUINN. Then I'd to suggest to our Committee, the chairman and the ranking member, that maybe after today's discussion that we look into that area of communication.

My other question was for Ms. Gwin as well. You talked in answer to a previous question about some ongoing treatment that's taking place right now, even though we're not going to wait for the culprit or the reason. Extensive treatment everywhere throughout the country? All veterans? Some veterans? Different areas?

Ms. GWIN. The VA Persian Gulf health registry is available to any veteran of the Gulf War who is no longer on active duty. DOD's comprehensive clinical evaluation protocol is available to all active duty members. These provide comprehensive diagnosis and treatment programs for veterans of the war who believe that they have service-connected symptoms.

Mr. QUINN. All across the country?

Ms. GWIN. All across the country. There are hierarchies of care. There is your entrance-level exam and treatment.

Mr. QUINN. That's one of the problems the veterans have, the hierarchy and the bureaucracy, et cetera, not directed at you, but that they have experienced throughout this. And that's what I'm trying to get at.

Ms. GWIN. We did hear a lot in our public hearings from veterans who had experienced lots of difficulties in acquiring care, both initially and in follow-up.

We conducted a series of site visits in 1995 and 1996, which is several years after those programs were initiated. We evaluated those programs at the time. We looked at them as being excellent. That is not to deny that many people had problems with those programs in the beginning.

Mr. QUINN. Very well. And part of that is mentioned in the report. Thank you. I appreciate that very much.

Dr. Russell, you talked about stress. This is probably more a comment than a question before I finish up. And a couple of the other members, Lane talked about stress and others have. I would just submit to the Committee and to the panel that if you think that stress was a factor in all of this while our veterans served, we ought to consider the stress they're under now not having answers, not being able to access the system once in a while, and the stress on their families and other members of their immediate home situations, so the stress when this whole thing happened, as you point out correctly. And that's a newer problem for us. But I also want to point out that there's a lot of other stress that's going on here.

Lastly—I know my time is up. I have some more questions further, Mr. Chairman. This is housekeeping maybe for the major. We say that the Presidential Advisory Committee on Gulf War Illnesses has been extended through October of 1997 to oversee exposure and implementations and recommendations.

Ms. KNOX. That's correct.

Mr. QUINN. I am not exactly sure about the funding of that until—I mean, that's only a few short, 6 or 7 months away. You're funded and operating up until then?

Ms. KNOX. Yes.

Ms. GWIN. We operate under an executive order.

Mr. QUINN. Right.

Ms. GWIN. The new order extending our life through October as far as producing work and then another 30 days for closeout was just issued.

Mr. QUINN. Okay. Thanks very much. I appreciate your answers. Thank you, Mr. Chairman.

The CHAIRMAN. The gentleman from Texas, Mr. Reyes, is recognized.

OPENING STATEMENT OF HON. SILVESTRE REYES

Mr. REYES. Thank you, Mr. Chairman. I, too, would like to submit a written statement for the record.

The CHAIRMAN. Yes, sir.

[The prepared statement of Congressman Reyes appears on p. 313.]

Mr. REYES. In the interest of saving time, I represent a district with approximately 60,000 veterans. And there is a deep sense of frustration that I think speaks to part of—as my colleague said, what's interesting to the language that you used, “superficial” and “lacked credibility,” I think in the context of what we're seeing that's coming out in the Gulf War Syndrome ailments, I guess would be the best way to describe it, and the interrelation to stress, all of these issues I think compound the feeling and the sense of frustration that veterans are feeling because they feel betrayed by their own government.

And, being a veteran myself, I know that combat is very stressful, but you place your trust in the leadership, in the ability of your commanders to provide the information to you. And part of the frustration that I think we're all feeling is the fact that subsequent to the stonewalling that has now come out, we feel that, even now, it's been a situation where it's like pulling teeth from DOD and in some cases from the VA.

I think that one question that I would like to ask, Ms. Knox, is: Do you believe that we will ever have accurate data on the wide range of exposures that our servicemen were exposed to in the Persian War? Is that something that is feasible or possible given what you know about—

Ms. KNOX. I don't think so. I don't think we had enough pre-deployment data in order to compare post-deployment relationships. Because we didn't collect that data prior to their service and then again afterwards, it's an epidemiological nightmare. You cannot go back and re-create that situation.

And, in comparison with Vietnam, that just dealt with one agent, Agent Orange, we have multiple risk factors that are involved.

Dr. RUSSELL. I agree with that. I don't think we're going to be able to relate environmental exposure in any precise manner to illnesses.

I might add that the stress of wartime doesn't end when the war is over. The stresses of demobilization and reentry into civilian life can be equally as devastating as the stress of combat.

If you add to that a lack of realization of the relationship between the stress-related illnesses and the service and access to care issues, then we have additional stress placed on this population. So we have a buildup of combat stress, post-deployment stress, and then issues revolving around access to health care and the issues of whether this is or is not related to service.

I feel that if we took more comprehensive, better care of the post-deployed population without attempting to determine up front whether they had a service-connected disability or not but just recognize that they were going to have illnesses post-deployment and deal with those illnesses and with whatever the state-of-the-art medicine is at the time, that we would mitigate a lot of these kinds of problems.

Mr. EVANS. Would the gentleman yield? Would the gentleman from Texas yield?

Mr. REYES. Yes.

Mr. EVANS. Ms. Knox, you said that there was a lack of pre-deployment data?

Ms. KNOX. Right.

Mr. EVANS. For future deployments, what kind of data should we be collecting during the pre-deployment period?

Ms. KNOX. I think in defense of DOD, they have done some of that pre-deployment data collection in Bosnia. They have done some environmental testing in the area that troops were deployed, and they have also done a better job of collecting, say, for instance, serum specimens prior to their service. And troops can be checked again following their service for any type of exposures.

Mr. EVANS. Thank the gentleman for yielding. Thank you.

Mr. REYES. Just as a matter of a follow-up and I think in the context of what we're doing here today and what has occurred before in these types of hearings, one of the comments we heard this morning from Commander Nier from the VFW this morning was an expressed desire that in issues that affect our veterans, that we err on the side of the veteran, instead of against them.

As a result of the information that you have been able to secure as a result of the committee findings, are you in a position to make a formal recommendation that we do that as a matter of practical policy in treatment and dealing with our veterans? Because I think that's a very important issue in the context of how our veterans, including those that are serving in the military now that are keeping us free as a nation—that's something in a way of reassurance to repair I think the damage that has been done by virtually what we have since found out regarding the Gulf War Syndrome.

Ms. KNOX. I am going to refer to Holly Gwin on that. I don't think that's in our charter.

Ms. GWIN. Well, in our final report, the committee does not make a specific recommendation that you err on the side of the veteran. But I think that if you look at our work, you will find that the staff as well as the committee approached all of the issues like that and emphasized the importance of providing care, even in the absence of knowledge about the cause. And in our presumptions that we made about chemical warfare exposure, we always thought that you should err on the side of the veteran.

Mr. REYES. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, sir.

The gentleman from Louisiana, Dr. Cooksey, is recognized.

OPENING STATEMENT OF HON. JOHN COOKSEY

Dr. COOKSEY. I can't help but notice that there has been more exposure to more chemicals in this war. Do you think it's related, number one, to the fact that we have more ability to find chemicals than we did in my era, in the Vietnam War era? Number two, when did veterans first come forward with these symptoms? My third question:—and you can divide these up as you see fit—How many deaths have been attributed to this syndrome or have there been any? First, the chemicals; second, the earliest symptoms; and, third, the number of deaths.

Dr. RUSSELL. I think the environmental exposures are not different in this war except for the nerve agents and the pyridostigmine bromide. Otherwise, I think the exposure in our era, sir, was equally great.

I'm sorry. I've forgotten—

Dr. COOKSEY. When did veterans first come forward with these symptoms?

Dr. RUSSELL. I think the 93rd ARCOM study was the first one. That was about 6 months after the—

Ms. GWIN. Nineteen ninety-two.

Dr. RUSSELL. Yes.

Ms. GWIN. Spring of 1992.

Dr. COOKSEY. And the third questions: deaths. How many deaths can you attribute to this?

Dr. RUSSELL. Since we can't define the syndrome, since there is no definition of a Gulf War syndrome, there are no deaths due to it. And the studies of mortality in the veterans population show equivalent mortality to a controlled population except for accidental deaths, which are elevated, which is true of all military post-deployment populations.

Dr. COOKSEY. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Doctor.

The gentleman from Arkansas, Dr. Snyder.

OPENING STATEMENT OF HON. VIC SNYDER

Mr. SNYDER. Thank you, Mr. Chairman.

Could we talk a little more about the Haley study? Are you all dismissing it or is it leading to ask further questions? What's the next step for research? I guess is what I'm saying. And what direction is that going on right now?

Dr. RUSSELL. We are not dismissing that. I don't believe anybody is. That's a very serious study. And these are good scientists, good physicians.

Mr. SNYDER. If I were a Gulf War veteran and I were having problems and I read that study, I think I would kind of get the sense of "Thank God. Somebody is finally getting on to something." So that's why—

Dr. RUSSELL. The problem is that the findings in the epidemiologic part of the study are based on subjective data and not objective data. And they're subject to serious problems with the population, series of—I'm not an epidemiologist. So I can't critique it in detail, but it does have epidemiologic—

Mr. SNYDER. If I can interrupt now, of course, this kind of study with those types of—I can't say the word either—those kinds of problems, a lot of times that's a funding problem in terms of being able to track down enough people from the unit, the ones that just didn't self-report, but kind of track down everybody. Is that what you're getting at?

Dr. RUSSELL. Well, I think there are very large epidemiologic studies ongoing. I think the other side of the issue is the toxicologic and neurophysiologic abnormalities that are found at a very low level.

Further studies of neurophysiology and following low-level exposure to the agents, argon phosphorus and similar agents, are definitely indicated. And there is a variety of experimental and medical ways of following up on these studies.

Mr. SNYDER. Are those ongoing now?

Dr. RUSSELL. I can't answer that.

Mr. SNYDER. Is funding adequate for that?

Dr. RUSSELL. I don't know. Probably.

Ms. KNOX. DOD has given a great deal of funding for that since they recognized that veterans were exposed to chemical munitions at Khamisiyah. Do you know the amount right off? I don't know.

Dr. BROWN. Yes. There are a number of studies that DOD has funded and is just starting to fund in the next fiscal year that are looking at this. I think, just to say again what Major Knox mentioned, the committee made a finding, a recommendation, that to answer some of the questions about low-level exposure and the combination of exposures from different agents, particularly the pyridostigmine bromide and chemical agents, for example, that there should be further studies done on this issue.

Mr. SNYDER. When I read your report—

Dr. BROWN. Haley's study is just the first, I think. I think there is going to be a whole slew of studies coming down the pipeline.

Mr. SNYDER. Probably with some dead ends along the way. When I read your report earlier today and you made that reference, was that your reference to the Haley study? Is that kind of an acknowledgment of that type of interest, the type of things that that study looked at and need to look at laundry detergents and insect repellents and flea collars and—

Ms. KNOX. Actually, Haley's report was not published until after we had completed our final report.

Mr. SNYDER. I got you. And just a couple of things that you all or one thing that you all said there, you said that you were only

dealing with one agent in Vietnam. And you made the comment that you thought there were several and that somebody remembers slapping on insect repellent. And God knows what our clothes were washed in.

I'm just wondering. Was there a little bit of disagreement between the two of you? I guess we didn't take antimalarial medicines and parasitic diseases were present. Was there a little disagreement between the two of you on Vietnam? I don't think that Vietnam was a controlled study with only one agent, I guess.

Ms. KNOX. No, it wasn't.

Dr. RUSSELL. No, it was not.

Ms. KNOX. Well, I think the veterans' complaint, though, was about Agent Orange during that era.

Mr. SNYDER. It was complaining about one chemical.

Ms. KNOX. Yes.

Mr. SNYDER. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Mr. Mascara, the gentleman from Pennsylvania, is recognized.

OPENING STATEMENT OF HON. FRANK MASCARA

Mr. MASCARA. Thank you, Mr. Chairman.

I happen to have been touched personally by this problem. A constituent of mine by the name of Mary Rhoads came to me. And we had quite an extensive conversation about her problems. They were very real. In the final analysis, we were able to get her 100 percent disability, but she's still out there fighting for others who have similar symptoms.

I'll just read here for a moment. She was 39 years old and served with the 14th Quartermaster Detachment in Greensburg, Pennsylvania, a community that I represent. She survived an Iraqi scud missile attack on her barracks which killed 13 members of her unit.

Since coming home, she has undergone a hysterectomy. She had her gallbladder removed. She has lesions from time to time that separate her from 12-year-old. She has vaginal bleeding, vomiting, and chest pains. She has a swollen stomach. In fact, I came to Washington, DC to introduce her to the President's commission. She testified here in Washington, DC.

I'm disturbed by the findings. The only thing you can find is psychosomatic, a stress syndrome that causes these diseases. I'm not a doctor. So I can't say that that is the case or not and how important that is to the issue before us.

The prior gentleman who asked you about the mortality rate among those people who served in the Gulf, I think your response was that nobody has died from that because you really don't know what the Gulf War Syndrome is. So you have no fatalities.

My question is it's my understanding that three individuals, all in the age 30 bracket, have died from myocardial infarctions. One 60-year-old died. Is the Department of Defense tracking those veterans who served in the Gulf War to see if there's any clustering of deaths in order to assist you in coming up with an answer?

I mean, 30-year-olds dying from heart attacks is not usual. So it's unique. Is the DOD tracking all 690-some thousand veterans to see who's dying, what they're dying from?

Dr. RUSSELL. There have been two published reports on follow-up mortality in this population. And I assume that this population will be followed very carefully from the point of view of excess mortality. So far with the exception of the accidental deaths, the mortality is not greater than a non-deployed similar population.

Mr. MASCARA. There is no concern about the three people serving in the Gulf who died from heart attack?

Dr. RUSSELL. I don't know. The heart attacks in young people are rare, but they do occur in all populations. And whether it's a statistically significant difference, I can't say.

The problem we have is—and your constituent is one of the problems—a 39-year-old person deployed will have post-deployment the expected illnesses of a 39 or 40-year-old person plus whatever exacerbation might be due to the stresses of the deployment.

Obviously she was in a very stressful situation. She may also have had some other medically important events occur in the Gulf, but they're very hard to separate from what happens in an ordinary population. It's a challenge of epidemiology.

Mr. MASCARA. It's not ordinary for me to be asked to help somebody in Florida but because Mary Rhoads had been given 100 percent disability, the Congress person from that district asked me if our staff would look into it. This woman suffered from similar kinds of problems. She eventually received 100 percent disability, a young lady from Florida.

I have one more question—perhaps Ms. Knox might be able to answer it—about the question of funding for the ongoing research and tracking of problems associated with the Gulf War Syndrome. Is the Department of Defense spending at a level that you feel is sufficient to do the job? And have there been instances where the money was available and the Department of Defense did not spend that money? And is there presently a commitment by the DOD to spend and to ask for whatever it takes so that we can maybe bring this thing to closure.

Ms. KNOX. Just a couple of things to comment on your previous discussion with Dr. Russell. We do appreciate you appearing in Arlington October of last year. I particularly remember Mary's testimony because she is also a nurse.

And I think, if I remember correctly, Mary had difficulty right at the time that she took the pyridostigmine bromide tablets. So our committee has recommended that further research be done on pyridostigmine bromide and their synergistic effects. And there are already studies that have looked at the synergistic effects of PB and stress, the Israeli study and then PB and DEET. Dr. Abou Donia out of Duke did that study. So I hope that that will answer some of those unanswered questions that we have about what the cause is.

As far as the appropriate amount of money to spend on this condition, I don't know if it's adequate to—

Dr. BROWN. Well, the committee found that, as Major Knox mentioned, the Federal Government does have a good mixture of studies ongoing and planned looking at Gulf War health issues and that the mix of studies includes the right studies on epidemiology; that is to say, looking at Gulf War veterans to see if there are illnesses or other problems at a greater rate than they should be and

also an emphasis on stress, looking at the long-term health effects, not just the psychosomatic effects, but the real physical health effects of stress. So I think the committee was very encouraged with the overall federal research portfolio on Gulf War veterans' illnesses.

In addition, just recently the Department of Defense released, recently within the last couple of months, a new request for proposals which, depending on how you add it up, has more than \$10 million attached to it. I guess I think overall the committee would not fault the amount of research, the emphasis on research that's going on now.

Mr. MASCARA. I see my time has run out, Mr. Chairman, but I hope we're not going down the same path as we did with Agent Orange.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, sir.

The Chair recognizes the gentleman from Minnesota, Mr. Peterson.

OPENING STATEMENT OF HON. COLLIN C. PETERSON

Mr. PETERSON. Thank you, Mr. Chairman.

I'm kind of new to all of this. So I may ask some dumb questions here, but I'd just like to make a comment first that I think that I've got a lot of folks in my office, I have a hospital in my district. And I think that most people out there wish that you'd spend more time studying why people feel like they're not getting adequate care, rather than studying whether they're compared to some other group or not.

I mean, is anybody doing that? Is anybody actually spending time figuring out why so many veterans feel like they're not getting this problem addressed? Has any time been spent on that?

Ms. KNOX. We looked at that a great deal, particularly early on in 1995. In September we held a meeting in Charlotte to look at the care that veterans were receiving, both in DOD and in the VA system, and examined the comprehensive clinical evaluation program that DOD provides for the soldiers and also the physicals that the VA is giving.

And, as Holly stated earlier, we were not able to do that right at the beginning, when they were in their biggest influx of veterans that came into the system. But when we did look at that in 1995 and 1996, we found it to be adequate.

Mr. PETERSON. Well, I can tell you there are still people coming to my office who are not getting the kind of care that they think they ought to get.

Ms. KNOX. Well, I think—

Mr. PETERSON. I think that more work needs to be done looking into that.

Ms. KNOX. I think maybe examining that presumptive period, veterans who are now experiencing illness that is beyond the 2-year limit, is an issue as well.

Mr. PETERSON. I'm trying to get a handle on just exactly what these commissions were supposed to do. This testimony here by Dr. Bailar, in here you say that, "You will note that the charge of our

committee did not include the study of the so-called Gulf War Syndrome."

Dr. RUSSELL. Correct.

Mr. PETERSON. What do you mean by that? It looks like every other place in the study you go in——

Dr. RUSSELL. We were unable to avoid looking at the Gulf War Syndrome and the science surrounding it, but the Institute of Medicine committees have very narrow charges usually. Ours was convened very early in response principally to the oil well fires.

So our charge was to determine whether the Department of Defense's and the Department of Veterans Affairs' ability to collect and maintain information and generate databases was going to be adequate to study the effects of the oil well fires and, by extension, the effects of health consequences from any environmental——

Mr. PETERSON. Did it actually say that you are not to study the Gulf War Syndrome in your charge?

Dr. RUSSELL. No. It didn't have any negative in it, but our recommendations were aimed at epidemiologic databases, information systems, epidemiologic investigations, and the quality of the research.

Mr. PETERSON. What confused me, I mean, I read that, and then I went on to read some of your other statements, where it looks like you have.

Dr. RUSSELL. We could not avoid it. It was impossible to carry out the charge without evaluating the hypotheses that were being put forward as explanations. And they came one after another about—I think there are about 16 different hypotheses now that had—and then we had to look at the quality of the investigations that pertained to those hypotheses, the research quality.

Mr. PETERSON. Well, I'm not a doctor. I have a hard time following all of this stuff. Again, I just would associate myself with some of the comments of my colleagues and just tell you that I think we still have a lot of work to do out there. There are people that I don't think are getting the kind of care.

And we ought to not just worry so much about why this all happened but get focused on getting help to the people who need it.

Ms. KNOX. If I could add, that is one of our recommendations, to look at the clinical follow-up of these veterans. And so the President has given us the authority to do that, to see if our recommendations are being followed.

Mr. PETERSON. Good. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, sir.

The gentleman from Florida, Mr. Stearns, is recognized.

OPENING STATEMENT OF HON. CLIFF STEARNS

Mr. STEARNS. Thank you, Mr. Chairman. And let me compliment you for having this hearing on the Gulf War Syndrome.

One of the first casualties of this syndrome was a Michael Adcock from my congressional district in Ocala, Florida. He was a 22-year-old young man in prime of health before he went there. He came back. He had played football in high school. And he suffered from nausea, skin rashes, aching joints, hair loss, bleeding gums, blurred vision, lack of energy. And he eventually died of a brain tumor at a very young age. So Mrs. Adcock has been up here.

Some of my concerns are—is either one of you a scientist?

Dr. RUSSELL. Here.

Mr. STEARNS. Because you mentioned earlier that the immune system—do you have a pretty good detailed background in the immune system and—

Dr. RUSSELL. I am an internist. And I've spent my career in infectious disease research.

Mr. STEARNS. It seems like some witnesses and people have said that the Presidential Advisory Commission did not have enough scientists on it. I think some of the witnesses today are coming in or have said that they relied too much on government-provided information and not enough scientific studies. Would you care to comment on that?

Dr. RUSSELL. I think the vast bulk of the scientific information we have available is from highly reputable scientists, whether in or out of the Government.

Mr. STEARNS. Weren't most of them in the Government?

Dr. RUSSELL. I don't believe so. I think, for example, that Dr. Haley's study from Texas is. And there's a substantial amount of work that's been done on government contract. There's a spectrum of scientific research capability within the Government that's very highly credible in the Department of Veterans Affairs and within the Department of Defense. And their colleagues in the academic community are contributing I think probably to an equal extent.

Mr. STEARNS. For example, did they check on the veterans coming in for hepatitis C?

Dr. RUSSELL. The issue with hepatitis C has—

Mr. STEARNS. Every veteran who complained about this, did he or she get an exam for hepatitis C? Can you be assured of that?

Dr. RUSSELL. I can't be certain of that. I know that hepatitis C is being extensively investigated by the DOD.

Mr. STEARNS. It's not just hepatitis C. There's A, B, C, D, E, F, G, and I think they're finding more.

Let me just change—

Dr. RUSSELL. C is a specific problem because of the gammaglobulin.

Mr. STEARNS. Yes, right. How much money is being spent by DOD presently devoted to the research funding for the Persian Gulf?

Dr. RUSSELL. I have no idea. I can't give you a number on that.

Ms. KNOX. Mark can give us that.

Mr. STEARNS. We have been told that it's approximately \$30 million. Do you have any way to know about it?

Dr. BROWN. It is something that we have tracked. I think it depends a little bit on how you define research. If you define research the way I define it, which is investigations of health effects and so forth, it's something in the neighborhood of \$15 million in fiscal years 1996 and 1997.

Mr. STEARNS. Shouldn't you folks or the VA be involved with this and not just DOD? Shouldn't there be a cross-pollination here or something? Have you been asked anything, the advisory council, asked anything by DOD about how to spend this money or anything?

Dr. BROWN. The group that's overseeing research is not DOD specifically. It's the research working group of the Coordinating Board, which has members at the cabinet level from VA and DOD and HHS. So there is an interagency oversight of this research program now.

Mr. STEARNS. So you feel that there's enough cross-pollination between DOD and the VA in dealing with the people who are actually coming into the hospitals? I mean, is there feedback from the veterans' hospitals so that DOD knows where to address things?

Dr. BROWN. I guess the best way I can answer that is to say that the research working group of the Coordinating Board has representation from VA and DOD.

Mr. STEARNS. Okay. One last question: Has there been a study of either the British, French, or Canadian particularly soldiers that went over there? Did they suffer the same thing? Has there been a similar type of phenomena of a syndrome?

Dr. RUSSELL. I understand there's an ongoing study in the British forces.

Mr. STEARNS. After all this time, there's no real conclusion that they have the same type of thing or not? From the advisory council, you haven't found that out?

Ms. GWIN. Our report includes information from the British and the Canadian clinical evaluation programs. And, in fact, the early data from those programs is very much like the data from our clinical programs with the same types of symptoms being reported by their veterans.

But the British have just gotten their epidemiologic studies underway. So it will be quite a while before we have any results from those.

Mr. STEARNS. And the French?

Ms. GWIN. We have been trying to get information from the French since we started working for this committee. And it's been—

Mr. STEARNS. To no avail?

Ms. GWIN. (continuing). Slow to come.

Mr. STEARNS. So the French won't give you anything. The British is just starting. And Canada has a similar phenomenon, a syndrome of this type. Is that fair to say?

Ms. GWIN. I don't know if it's fair to say they have a syndrome. They have reported clinical data that looks very much like the U.S. clinical data.

Mr. STEARNS. Okay. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Stearns.

The gentleman from Massachusetts, Mr. Kennedy, is recognized.

OPENING STATEMENT OF HON. JOSEPH P. KENNEDY II

Mr. KENNEDY. Thank you very much, Mr. Chairman. I want to thank you very much for hosting this hearing today and let you know how much we appreciate it and look forward to many more in the future, Mr. Chairman.

I want to just deal with what I think is sort of an underlying concern that many of the veterans that I think we hear from on a regular basis have about how this whole process has developed.

First of all, I wonder if you could comment, Ms. Knox, on why you feel that this took 6 years for the Government to acknowledge. And, more specifically, I wonder if you might tell us about the extent to which you feel that you have really covered any possible coverup that could occur by the Government with regard to potential chemical or biological exposures.

We have heard about the Khamisiyah exposures that, as I understand it, did not come through your particular organization but, rather, came about as a result of some CIA documentation.

I've been contacted. A number of us have been contacted over the years with regard to sort of incidental kinds of occurrences that took place that have I think created a general atmosphere of mistrust between the veterans and the government.

And I wonder if you can just address directly whether or not you feel that you have gotten a handle on the extent to which these illnesses could possibly be caused by something other than stress.

Ms. KNOX. To answer your first question, we are not the first committee to look at Gulf War veterans' illnesses. Actually, we are the fifth committee to look at Gulf War veterans' illnesses. Dr. Russell worked with the IOM committee. So it has been studied a great deal.

I do agree that DOD's failure to come forward with chemical exposure at Khamisiyah definitely causes an area of mistrust in the veterans. In addition to that, one of the things that we had tried to find out from the Persian Gulf investigation team was where troops were located so that we could look at the realm of veterans that could have been exposed.

So along with that lack of data as to where troops were located and what chemicals were there and to what degree they were exposed, we cannot answer that.

Mr. KENNEDY. I appreciate your response, Ms. Knox, because I was going to get through and I asked the staff here if they could—you know, you say that it's a number of different committees that you are aware of. There have been more different sort of fits and stops on behalf of the Congress and a number of others that have sort of looked at this whole issue.

I remember going back to a point where we had the fellow who actually did the Agent Orange study, the first fellow who ever came before this Committee to talk about it, said there was absolutely nothing to this whatsoever and that it is just—"malingers" is a word that he used in terms of describing what the problem was.

I think that if you look at just the whole series, whether it's the group, the symptom of the Pennsylvania Air National Guard or you look at the birth defects in Mississippi, if you look at the individuals who have contacted almost every member of this Committee with a series of complaints, and then you were told that we're supposed to sort of characterize this in general terms as sort of stress-related, it just seems to me that—I don't know if anybody had ever mentioned to you any of the people who fought in War World II and the like that had to land on the beaches in Normandy and all the rest of it, whether or not there were any similar kinds of stress-related problems.

I mean, I think we're all sort of aware of PTSD and other issues that came as a result of the Vietnam War, but I'm wondering

whether or not we ever saw anything like the degree to which we see these kinds of issues just in this particular conflict.

Ms. KNOX. I just want to reiterate that we say stress is a contributing factor. We don't think it's the cause of Gulf War veterans' illnesses. And we recommend that further study needs to be done on the physiological response to stress.

Mr. KENNEDY. I don't mean to cut you off, and I know that Dr. Russell has got something to say. But because my time is running out, what I do want to suggest is that when you are running a presidential commission on this issue, it has the weight of the entire Federal Government and the responsibility to sort of be almost the sort of final say in what has occurred.

And I think that this is an issue that if you are not feeling that you have your arms around every possibly explanation, including whatever secret documents might be available, including every possible lead that should be run down to make the determination as to whether or not there is some kind of cause that has not been fully exposed to all of the veterans and to the American people, there's a responsibility that I think rests squarely on your shoulders. And anything that we can do to help you get that information, I think you should feel like you should come to us and ask for it. And this is an opportunity for you to do that.

So I really want you to make sure that you answer the question whether or not you feel that you have at this time exhausted and have a full sort of accounting of everything that could possibly have contributed to this and whether or not we're at least in a process of having that be completely aired.

Ms. KNOX. Well, I don't think we can ever have a full account of what occurred. Just as it took until 1996, to hear about Khamisiyah, I would think that there might be other things that might evolve or come about that we might discover at a later time. Hopefully we'll discover that before the end of our charge.

Holly, you might want to add to that. I don't—

Mr. KENNEDY. Well, Mr. Chairman, I'll finish up.

But I just don't think it's acceptable that we have a circumstance where the presidential commission is not coming in and reporting back to the Congress as to the full extent of what this has been about.

We've spent millions and millions of dollars. We still don't know what's going on. And here's the chairwoman of the committee saying that we're going to hear more and more about this in the future. I just think that this should not be as difficult a job as it seems to be coming across.

The CHAIRMAN. I thank the gentleman.

Dr. Cooksey, did you have a quick question?

Dr. COOKSEY. Mr. Chairman, I know I've already had a question. Just a comment from someone who's older and been around a little bit longer and also is a physician.

Some of us here are old enough to remember the days of polio. There were a lot of unanswered questions about polio. And when I was a kid, my parents did a lot of crazy things to protect me from polio. And we later found out the answers.

I personally feel that veterans, particularly the Persian Gulf veterans, should have everything that they're entitled to in the way

of a disability claim. But as physicians, we don't always know the answers to these questions. And I think that needs to be brought into perspective.

Mr. KENNEDY. If the gentleman would yield just briefly?

Dr. COOKSEY. And sometimes it takes the time to get the answers to these questions.

Yes, I will yield.

The CHAIRMAN. If the gentleman has a direct response very quickly.

Mr. KENNEDY. Yes, very briefly. You've been around on Earth a lot longer than I have, Doctor, but I have been around here long enough to know sometimes it's hard to get straight answers from people who come before this Committee and a lot of other committees. And it's good to keep your left hand high when you're dealing with them.

Dr. COOKSEY. I've been here 10 years longer.

The CHAIRMAN. The gentleman from Alabama, Mr. Bachus, is recognized.

OPENING STATEMENT OF HON. SPENCER BACHUS

Mr. BACHUS. Thank you, Mr. Chairman. I do want to compliment you on holding this hearing. And I appreciate the panelists.

I have a statement, but I don't want to take time on my views. I just want to get right to what y'all think, "y'all" being an Alabama express.

Now, we had an ammunition dump that blew up in Iraq in March of 1991. And almost immediately when the Gulf War veterans returned, we had 40 or 50 thousand of them who were sick. And people started asking the question: Was there chemical exposure? And until June of 1996 we were told no. So you're talking about from March of 1991.

There's now been a recognition by the Pentagon last June that as many as 20,000 of our troops were exposed to chemical exposure in the March 1991 incident.

My question is this. Maybe I'll direct it to Major Knox. I want to commend the presidential committee on really coming to the conclusion that the Pentagon knew before June that there had been this exposure but they didn't say anything until June.

My first question would be to you. This was a concealment for some period of time. Does this constitute a coverup? I know that's a tough question.

[The prepared statement of Congressman Bachus appears on p. 297.]

Ms. KNOX. Well, I certainly think it generated mistrust on both the public and the veterans' view. The CIA was helpful as was UNSCOM in coming to that finding and bringing it to us. So certainly that's one of the biggest issues that has created this atmosphere of mistrust.

Mr. BACHUS. But there was a concealment at the Pentagon of this chemical exposure.

Ms. GWIN. We were able to pull together enough information for the committee to reach a conclusion that there was only a superficial effort, at best, to disclose the information.

Mr. BACHUS. Well, that's a concealment.

Ms. GWIN. Well, we did not go so far as to say there was any attempt to conceal.

Mr. BACHUS. Well, wasn't their foot dragging? I mean, we were constantly asking: Were they exposed chemically? I mean, there was a concealment. What kind of military thinking led to a concealment like this or a coverup?

Let me just ask you personally. Do you think there was a cover-up?

Ms. KNOX. Not personally, I don't.

Mr. BACHUS. Do you think there was a concealment?

Ms. KNOX. I think it was ineptness.

Mr. BACHUS. Was what? Ineptness?

Ms. KNOX. Yes.

Mr. BACHUS. Over a major issue that was being debated in this country with 40 or 50 thousand sick veterans, there was just an ineptness?

Ms. KNOX. That's really difficult for me to answer.

Mr. BACHUS. I can understand I'm putting you in an embarrassing situation, but can you see how we would conclude that there's been a coverup or concealment?

Ms. KNOX. Yes, sir, I understand.

Mr. BACHUS. And now let me move beyond that. Well, let me ask you this: What kind of military thinking led to this ineptness? Is the Pentagon inept?

Ms. KNOX. I just said they were.

Mr. BACHUS. All right. [Laughter.]

Dr. Russell.

Dr. RUSSELL. I have no knowledge of how the information was transmitted from the CIA, the origin of the information, at what level in the civil establishment we call the Defense Department. And I don't know where the fault lies.

I must say our committee was very unhappy about having been kept in the dark.

Mr. BACHUS. Right. Kept in the dark, foot dragging, concealment, coverup, whatever it was, what institutional changes do you think can be made at the Pentagon to see that this doesn't happen again?

Ms. GWIN. This Committee has been extended in part to oversee the activities that DOD has put in place now. They have expanded their investigative team substantially, I guess almost tenfold. They have devoted much more money to the investigative effort as well as—

Mr. BACHUS. So you're sort of monitoring them and investigating the investigators or—

Ms. GWIN. We are overseeing their activities as well as trying to conduct some of our independent investigations so that we can make sure—

Mr. BACHUS. Okay. Thank you.

Let me ask another question. Now that we've got the chemical exposure and there's proven chemical exposure, now there's a question of the link between that and the illnesses that our veterans have. The University of Texas study that's come out recently appears, at least my thought is, that that conclusively provides a link between some of this exposure and some of these illnesses. Dr. Russell, is that?

Dr. RUSSELL. I don't believe there—what has been proven is a release of chemical agent into the atmosphere when the munitions dumps were destroyed. Whether there was any true exposure or not has yet to be determined.

Whether that population that was exposed has medical outcomes any different than the rest of the population that was in the Gulf anywhere near those dumps, I don't know the relationship between the patients that Dr. Haley studied and that monition dump. But I think I know that they weren't anywhere near there. So we can't draw any cause and effect relationship. No, sir.

Mr. BACHUS. Would you agree that that was a significant study?

Dr. RUSSELL. I think it was a significant study. It will require extensive follow-up and replication by other scientists.

Mr. BACHUS. Thank you.

And, finally, this is my last question. There have been reports that VA doctors who have studied the Gulf War Syndrome have been fired from the VA system. You all may have heard of those reports. They say that this was retaliation. Would you all make any comment? Are you aware of those reports?

Ms. GWIN. We are aware of the reports. We have not reviewed as a committee the basis for them.

Mr. BACHUS. Don't you think that should be done? And who should do that?

Ms. GWIN. The committee hasn't reached a conclusion about that.

Mr. BACHUS. Would you take a look at that? Thank you.

The CHAIRMAN. The gentleman from New Jersey, Mr. Smith, is recognized.

OPENING STATEMENT OF HON. CHRISTOPHER H. SMITH

Mr. SMITH of New Jersey. Thank you very much, Mr. Chairman.

A couple of questions. And many of the more important questions have been asked already. And I appreciate my colleagues zeroing in on those questions. Major Knox, one of our witnesses today, Mr. Ford, will make the comment that a majority of the funded Gulf War studies and nearly half of those completed that were related to stress, that "It's not surprising," to use his words, "that the Presidential Advisory Committee found stress to be an important contributing factor."

And also in testimony today the commander-in-chief of the Veterans of Foreign Wars, Mr. Nier, states, "We, the VFW, find it unfathomable as well as counterproductive to insist that stress is the predominant cause. These elements are nothing more than, in the veterans' heads, an insult." And then it goes on to develop that theme.

How do you respond to that?

Ms. KNOX. Well, again, in our report we state that we need to look at stress in more detail, the physiological effects of stress. And that was one of the largest areas of funding that DOD did. Of course, the results of that are not in.

But that was one of the three findings that we made that stress was a contributing factor. We do need to look at PB and the synergistic effects and also low-level chemical exposure.

Mr. SMITH of New Jersey. Again, Mr. Ford raises a question today—and, again, looking at their testimony, they do raise some

questions that ought to be highlighted here—that “The Presidential Advisory Committee’s findings are questionable because it included individuals who are not scientists and because it relied heavily on government-provided information.”

How do you respond to that, particularly the latter part of that?

Ms. KNOX. As I said in my opening statement, all of the panels that we heard had peer-reviewed research included. Our committee includes scientists.

Mr. SMITH of New Jersey. So you believe you had sufficient resources to do the job?

Ms. KNOX. I think we did.

Mr. SMITH of New Jersey. Let me ask one final question. Your committee recommends that the VA should seek statutory authority to treat veterans and their families for reproductive problems caused by their service connection. You don’t include abortion in this list of services, do you?

Ms. KNOX. I’ll have to refer——

Ms. GWIN. The service we specifically identify is genetic counseling.

Mr. SMITH of New Jersey. Okay. But what about abortion?

Ms. GWIN. The committee did not consider abortion. We specifically recommended that genetic counseling be included in this.

Mr. SMITH of New Jersey. Okay. Thank you. I yield back the balance of my time.

The CHAIRMAN. Thank you, sir.

The gentle lady from Idaho, Ms. Chenoweth, is recognized for 5 minutes.

Mrs. CHENOWETH. I won’t be using my 5 minutes. I just have one question. But I do have a statement that, with your permission, I’d like to enter into the record.

The CHAIRMAN. Certainly will.

[The prepared statement of Congresswoman Chenoweth appears on p. 314.]

Mrs. CHENOWETH. Thank you, Mr. Chairman.

My question is this to Ms. Knox: Can you foresee that any of the records involving this subject in the Pentagon would be considered classified or would have any other kind of classification on them so that people would hesitate to send them to either us or to people who have been suffering from Gulf War Syndrome, their own records with regard to medical records?

Ms. KNOX. Is your question: Would the medical records be classified?

Mrs. CHENOWETH. Either medical records or procedures that this Committee may want with regards to how things are handled.

Ms. KNOX. Not that I’m aware of.

Ms. GWIN. The only medical records that we came into contact with that had at one time been classified were the records of the vaccines, Anthrax and botulin toxoid vaccines, that were given to the troops.

Mrs. CHENOWETH. Ms. Gwin, do you see any problem with that now? Is it the policy of the Pentagon and the Department of Defense to make sure that any patient who requests medical records or who requests information with regards to procedures or vaccinations or anything be afforded that information?

Ms. GWIN. We believe the policy of DOD and VA is to make medical records available to the individuals to whom those records apply.

Mrs. CHENOWETH. Mr. Chairman, I do have records here that have been stamped that read, "These documents or records or information contained herein are deemed confidential and privileged under provisions of 38 USC 3305 and VA Regulation 6500 through 6540, which provides for fines up to \$22,000 per violation." This material shall not be transferred to anyone without proper consent or authorization as provided for by law or regulation.

And I know that the Committee through the subpoena process can probably eventually get what we need. But I am also concerned that the process is not set up in DOD or the Pentagon. So our veterans cannot get all the records that they need to—

Ms. GWIN. I am not absolutely sure, but I think that citation is to a Privacy Act concern, not to classification.

Mrs. CHENOWETH. Thirty-eight USC 3305?

The CHAIRMAN. The Chair I think can answer that, I think there's a statute that prevents the VA from releasing these records. It's kind of like the Privacy Act—it does not prohibit the individual from seeing it, but the VA cannot release those records to other people.

Mrs. CHENOWETH. Okay. Mr. Chairman, my concern is that the victims of Gulf War Syndrome had a very difficult time in getting their own records or because this was stamped on their records. And people who would have otherwise issued them didn't want to be fined \$20,000.

The CHAIRMAN. In my understanding, that should not be the case for the individual to get his records. He is certainly eligible to get those records.

Mrs. CHENOWETH. Well, Mr. Chairman, that's the reason that I wanted to be sure and bring that up now—

The CHAIRMAN. Thank you.

Mrs. CHENOWETH (continuing). So that it won't happen in the future.

Mr. EVANS. Mr. Chairman, I also understand, at least during my time, the service said you had all your medical records that you took with you from command to command and when you were discharged, they hold onto them. But you can easily obtain those. If that's a problem, individuals should see their local member of Congress.

Mrs. CHENOWETH. Thank you. And, Mr. Chairman, I will be entering this also in the record later.

The CHAIRMAN. Thank you.

The CHAIRMAN. Mr. Bachus, you got here just in time to be the last one on this panel. Thank you, sir.

Dr. Russell and Major Knox, Ms. Knox, and Ms. Gwin and Mr. Brown, we thank you for your time this afternoon. There will probably be questions from members and staff of the Committee. We would appreciate a rapid response, if you would, please. And thank you very much.

Dr. RUSSELL. Certainly.

Ms. KNOX. Thank you, sir.

The CHAIRMAN. Our next witness is Commander Nier. And while he's coming up, let me remind the members that this first panel has taken a little over an hour and a half. If you could, please refrain from asking other members to yield so as to not use their time. It would be appreciated if we move very rapidly through this. We have four panels to go.

Commander Nier is the Commander-in-Chief of the Veterans of the Foreign Wars. We're happy to have you with us, Commander. And, if you care to introduce anyone or if you want to proceed, your entire statement will be made a part of the record. If you can summarize, it would be appreciated.

Mr. NIER. Thank you, Mr. Chairman, and members——

The CHAIRMAN. Let me just give it one second for these members so as not to be interrupted.

Go ahead, sir.

Mr. NIER. Thank you, Mr. Chairman, members of the Committee.

STATEMENT OF JAMES E. NIER, COMMANDER-IN-CHIEF, VETERANS OF FOREIGN WARS OF THE UNITED STATES; ACCOMPANIED BY KEN STEADMAN, EXECUTIVE DIRECTOR, VFW WASHINGTON OFFICE, AND JOHN GWIZDAK, LEGISLATIVE CHAIRMAN

Mr. NIER. Yes, I would like to introduce the two gentlemen who are with me. On my left and your right, Mr. Ken Steadman, the Executive Director of our Washington office; and on my right and your left, Mr. John Gwizdak, my legislative chairman from the great State of Georgia.

The CHAIRMAN. Thank you, sir.

Mr. NIER. As you are aware, it was my privilege earlier today to express the views of the Veterans of Foreign Wars before a joint hearing on the Committees on Veterans' Affairs regarding veterans programs and entitlements. It is now my honor to come before this Committee on behalf of a very special segment of the veteran population: those brave young men and women who served so honorably and well in the Persian Gulf.

A number of these individuals are suffering from as-yet-undiagnosed disabilities collectively known as Gulf War Syndrome. The VFW is unalterably committed to seeing this Nation spare no effort in coming to the aid of these veterans. We insist that Persian Gulf veterans receive all the health care and compensation that is there due.

Yesterday afternoon the VFW hosted a major forum within the context of our Washington conference addressing Gulf War Syndrome held at the Sheraton Washington Hotel and facilitated by VFW staff. Senior representatives from the President's advisory committee, DOD, the VA, Centers for Disease Control, and concerned VSOs took part. I can tell you that this forum was an enormous success. And we fully intend to continue in this vein.

The VFW has for some time pushed for the extension of the life of the President's Advisory Committee on Gulf War Veterans' Illnesses, which has served so ably in overseeing and coordinating the effort to resolve this issue. We are highly gratified that the President has heeded our request by extending the committee's operation another 9 months.

While Gulf War Syndrome is now fully recognized in the scientific and medical communities as a legitimate disease, its cause and cure have continued to remain elusive. One serious obstacle to properly resolving this issue has been its far-from-adequate handling by the Department of Defense.

At least early on, DOD simply refused to give Gulf War veterans' own reports of ill health symptoms and possible toxics exposure episodes the credence they deserved. Further, DOD's failure to come forward in a timely manner with information showing that a large number of our troops in the Gulf may have come into contact with chemical and biological agents has surely impaired relevant scientific research.

Perhaps even more detrimental, however, is the climate of uncertainty and even distrust this has created among Gulf veterans themselves. Many perceive themselves to have been deliberately deceived and will call into question almost information that COD now provides. This has rendered an already troublesome issue much more difficult and indeed represents an affront to the sacrifice and service of all of this Nation's veterans.

The VFW demands that all relevant data on the Gulf War experience be provided to the appropriate scientific and public entities as soon as it comes to light.

The VFW is also deeply concerned over the high denial rate for Gulf veterans seeking VA compensation for undiagnosed illnesses. While it is our understanding that some of these veterans now receive compensation for diagnosed disabilities, the 95 disallowance rate for undiagnosed illness claims strikes us as implausibly high.

We insist that no Gulf veteran in need be left out in the cold because of our as-yet inadequate understanding of Persian Gulf Syndrome. An important step in this regard would be the expansion of the current 2-year presumptive period in which Gulf War Syndrome must manifest in order for a veteran to receive VA compensation. In light of the medical, scientific, and factual uncertainty surrounding this issue, this manifestation period is both overly restrictive and scientifically unsound.

The VFW urges the immediate establishment of an open-ended presumptive period for Gulf War Syndrome. The VFW also supports the establishment of a case definition for Gulf War Syndrome. This would, at the very least, allow veterans benefit administration to take individual symptoms associated with service of the Gulf under consideration collectively.

Whereas, when taken individually these disabilities may not fall within their assigned manifestation periods, taken together they may represent a compensable manifestation of Gulf War illness. Further, this would compel VA doctors to more thoroughly assess the etiology of Gulf veterans' disabilities, thereby improving the rating process.

Mr. Chairman, it would be remiss of me if I did not at this time commend the strong bipartisan effort of the Congress as well as the administration in addressing this issue. Standing in stark contrast to the handling of Agent Orange many years ago, this Nation's lawmakers have been swift and vigorous in working to provide veterans suffering from Gulf War Syndrome the care and compensation they need and they deserve.

I thank and congratulate you for your accomplishments thus far. Be assured the Veterans of Foreign Wars will continue to work together with you and will not relent until the Persian Gulf issue is fully resolved.

Thank you very much.

[The prepared statement of Mr. Nier appears on p. 326.]

The CHAIRMAN. Commander, thank you for your statement. We look forward to working with you and your membership.

Do any members have questions? Mr. Evans?

Mr. EVANS. No, Mr. Chairman.

I appreciate the commander's insistence that we extend the filing date. That's very important. I hope we'll work on that in this Congress.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Quinn, I'm just going to bounce back and forth. I don't know. Any questions of the commander?

Mr. QUINN. Thank you, Mr. Chairman.

No questions at this time. We heard your testimony this morning at the hearing, Mr. Commander. We appreciate your time very, very much.

Mr. NIER. Thank you very much, sir.

The CHAIRMAN. Mr. Kennedy.

Mr. KENNEDY. Thank you, Mr. Chairman.

Commander, first of all, I wanted to just apologize for not being able to be with you this morning. I was at a meeting at the White House. And I apologize for not being there, but I look forward to having an opportunity to read your testimony.

Further, I just wanted to ask one brief question, which is whether or not your current sense of the health care that is being provided to the veterans that are a part of your organization that have this particular syndrome is, in fact, being dealt with adequately by the VA.

Mr. NIER. No, sir, we do not. We think it's inadequate. It's our goal to ensure that these veterans receive the care and compensation they deserve. And right now we're not happy with the 95 percent disallowance rate.

Mr. KENNEDY. Can you just explain a little bit more about what you feel the implications of that 95 percent rate are? In other words, why are they being turned down? Is your sense that there is still an attitude by the VA itself of not recognizing this as a legitimate illness or what is your sense of why people are not getting properly cared for?

Mr. NIER. It's my sense, sir, that it's the presumptive period. That's why we want it extended.

Mr. KENNEDY. But the presumptive period because Mr. Evans and I and the Chairman worked on this last year would only cover, as I understand that issue—Mr. Chairman, maybe you can help me if I'm wrong about this, but I thought that that only dealt with those individuals who would be coming forward now who had not previously felt that they had illnesses that related to their service in the Gulf. Is that really the only category of veterans that you're suggesting are not being properly cared for or are there, in fact, others who are just going in and are feeling like they're not getting—you know, they go in and they say, "Listen, I've got these

complaints," that they did, in fact, register but they're just not getting the proper care?

Mr. NIER. Yes. Our concern is, Senator, that it could be when the——

Mr. KENNEDY. My uncle would not be pleased with that one, Mr.——

[Laughter.]

Mr. NIER. I'm sorry.

Mr. KENNEDY. The Chairman probably would be just as happy to have me move out, but anyway.

Mr. NIER. Sorry. The coming forth of the veterans with individual symptoms may not have been granted the compensation. We feel that they now should be looked at with collective symptoms. And perhaps they would be eligible for the compensation and care.

Mr. KENNEDY. I could pretend I understood what you just meant by that. Can you just explain that for a second, please?

Mr. NIER. Well, they could have come forth early on with a symptom that was not recognized as compensable by the VA.

Mr. KENNEDY. I see.

Mr. NIER. Later they may have come forth with more symptoms that looked at collectively may——

Mr. KENNEDY. I see. But it is really the category of veterans that have the requirement or the need to actually declare themselves victims of the syndrome at this stage, rather than people who have been treated in the past who have declared themselves to be victims of the syndrome. You're feeling that those veterans, which I think would be the vast majority of the ones that are being cared for by the VA, are getting adequate care? I'm just trying to get an understanding of what you're suggesting.

Mr. NIER. I think so, yes, sir.

[The information follows:]

To date, approximately 2000 Guard/Reserve members have completed diagnostic evaluations through the CCEP; however, the number of individuals who may be in need of follow-up care is unknown. Guard/Reserve personnel have limited entitlement to follow-up treatment within the MHSS unless they have a medical condition which can be shown to be service connected according to strict criteria. Provisions of Public Law entitle any Persian Gulf veterans who may have been exposed to a toxic substance or environmental hazard to receive follow-up care through the VA. The Department will be working with VA to make certain that Guard/Reserve personnel evaluated through the CCEP are aware that they may apply for follow-up care through the VA system.

Mr. KENNEDY. Yes.

Mr. NIER. Right.

Mr. KENNEDY. Okay. Thank you very much.

The CHAIRMAN. Dr. Cooksey, do you have questions?

Dr. COOKSEY. No, no questions. Thank you.

The CHAIRMAN. Thank you, sir.

Mr. Peterson, no questions? Who's next? Mr. Bilirakis, do you have a statement?

Mr. BILIRAKIS. Just one, Mr. Chairman. I guess it's more a follow-up to Mr. Kennedy's.

Is it your feeling, your strong feeling—I know you referred to the study, the presumptive period. But is it your strong feeling that if that were extended, that it would probably pick up an awful lot of the disallowances——

Mr. NIER. Yes, sir.

Mr. BILIRAKIS (continuing). By the problems?

Mr. NIER. Yes, sir.

Mr. BILIRAKIS. Do you have any feeling as a result of your own research and whatnot as to what that period should be?

Mr. NIER. Yes. We have our own Gulf War registry. And we are really pursuing this issue within our organization.

Mr. BILIRAKIS. Okay. But you have no recommendation to this Congress in terms of whether it should be 3 years, 4 years, or—

Mr. NIER. Open-ended. Yes, sir, we do.

Mr. BILIRAKIS. Open-ended?

Mr. NIER. Open-ended. Yes, sir.

Mr. BILIRAKIS. I see.

Mr. NIER. That's our recommendation.

Mr. BILIRAKIS. All right. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Dr. Snyder? No questions. Mr. Peterson? No questions. Bob Filner?

Mr. FILNER. Thank you, Mr. Chairman.

I apologize for missing your statement. I heard you this morning. So I'm sure I agree with everything you said. But let me tell you why I missed your statement. And I'd like to have some advice on this because it seems to exemplify the problems that people are dealing with or having with the establishment, as it were, the folks who are supposed to be helping us out of this.

I was meeting with a couple of your members from California, very serious people, looked to me very credible,—they had one of your hats on; so I assume they were very credible—explaining to me that a set of doctors that they knew working both in Texas and in California had because of relatives who had come down with these symptoms got very personally involved with the research, et cetera, and had developed some laboratory tests that involve tests that most doctors wouldn't either know about or how to do. They have to do with white cell testing, DNA prints, and claim to have been able to diagnose the set of symptoms in some very precise ways and then treat them in very successful ways. And they have case studies now up to 6,000. The way they relayed it to me they have not been able to get an official hearing on what exactly they're doing and the success they've had.

Now, does that sound credible to you, that story? and what is the problem with people who are seeming to make gains in this not getting a respectful hearing about things that might help thousands and thousands and thousands of people? Does this story sound at all credible?

And what should we do about it? I'd like to ask both you and the Chair: If there is something to this, how do we get these stories out here?

Mr. NIER. I do not know. I can't respond to the credibility. I would think it is, sir, if it came from VFW members. Who were they asking for the hearing with? I'm not quite sure.

Mr. FILNER. I didn't have time to go over the full story because I want to come back and talk to you. But they were explaining their studies had been submitted to the Pentagon and to the commissions. And people were just not paying any attention because

these were not doctors within the normal network or the normal establishment, as it were.

Mr. NIER. I am just being told that we have encouraged the VA to look into this. It's a Mr. Garth Nicholson, I believe you said, a microbiologist?

Mr. FILNER. I think so.

Mr. NIER. So that story is, in fact, credible. And we are encouraging the VA to meet with them, sir.

Mr. FILNER. I hope we as a Committee or as a group could encourage that. It sounded to me to be very real. The response that they have encountered sounded to me typical of some of the defensiveness and inability to accept things outside the normal chain of command but might have success. At least it's worthy given what we are dealing with as a nation of some interest.

The CHAIRMAN. Mr. Filner, we have members of the VA here today. And you can ask them that question.

Mr. FILNER. Thank you very much. I appreciate it.

I yield to Mr. Evans, please.

The CHAIRMAN. Mr. Evans.

Mr. EVANS. I understand Garth Nicholson's concerns are being investigated by the United States Army at this point, not the VA, that they're looking into it.

Mr. FILNER. I am not certain this is the right name or not, frankly, but we—

Mr. EVANS. Is that the name?

Mr. FILNER. I'm not sure. That's what they think they—

Mr. NIER. It is one of several, sir.

Mr. EVANS. The VA is also funding some studies. I think you can direct your questions to them when they come up—

Mr. FILNER. Fine. Thank you.

Mr. EVANS (continuing). About some studies that they are going to fund in the next fiscal year.

The CHAIRMAN. Are there other questions? Mrs. Chenoweth? Mr. Bachus? Spencer?

Mr. BACHUS. Thank you.

Commander, this 95 percent that we hear, is this of all disability benefits or these are just the mysterious illnesses, undiagnosed, or is this all of them?

Mr. NIER. All of them, sir.

Mr. BACHUS. But that's the total of—

Mr. NIER. That's correct.

Mr. BACHUS (continuing). Over what? Over 7,000. And we've only had about 400 of them honored?

Mr. NIER. Right.

Mr. BACHUS. Are you familiar that the GAO took a look at that, the reasons for these denials? Have you all reviewed the GAO's—do you all have any comment maybe on the GAO study?

Mr. NIER. Go ahead, Mr. Steadman.

Mr. STEADMAN. Sir, we are familiar with that. Our staff is reviewing that currently, taking a look at what GAO had to say about it.

Mr. BACHUS. How does this 95 percent figure, say, correlate to earlier wars and disability claims under those wars, say Vietnam?

Mr. NIER. We think it's inordinate, but I would suggest you ask the VA that, sir.

Mr. BACHUS. Okay. I think it would be important to—

Mr. NIER. Yes, sir.

Mr. BACHUS (continuing). Take a look at how it varied.

Also, we did note that a lot of the veterans were never told that they had to give evidence that this manifested itself within 2 years, which we have now extended. Do you think this played a big factor? Do you think—

Mr. NIER. Yes, definitely.

Mr. STEADMAN. One of the Presidential Advisory Committee's interim findings was that both DOD and VA needed to expand their outreach efforts.

Mr. BACHUS. Thank you.

The CHAIRMAN. Thank you, sir.

Mr. Bishop, did you have any questions? You're the last one on this panel or we'll go to the next panel if you don't.

Mr. BISHOP. No, no. I'll pass.

The CHAIRMAN. Thank you, sir. Gentlemen, thank you. Commander, we hope to see you later on this evening.

Mr. NIER. Thank you, Mr. Chairman.

The CHAIRMAN. If we could have the third panel, then, please, to come up? Dr. Garthwaite, the Deputy Under Secretary of Health, Department of Veterans Affairs;—this may be the appropriate time to ask that question you just asked, Spencer—Dr. Rostker, special assistant to the Deputy Secretary of Defense for Gulf War Illnesses from the Department of Defense; and Dr. Jackson at the National Center for Environmental Health, Centers for Disease Control and Prevention, Department of HHS.

Gentlemen, your entire statements will be submitted for the record and will be printed in the record in full. We would appreciate it you could summarize within the 5-minute time limit. Dr. Garthwaite.

STATEMENTS OF THOMAS GARTHWAITE, M.D., DEPUTY UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS; STEPHEN C. JOSEPH, M.D., M.P.H., ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, DEPARTMENT OF DEFENSE; DR. BERNARD ROSTKER, SPECIAL ASSISTANT TO THE DEPUTY SECRETARY FOR DEFENSE FOR GULF WAR ILLNESS, DEPARTMENT OF DEFENSE; AND RICHARD J. JACKSON, M.D., M.P.H., NATIONAL CENTER FOR ENVIRONMENTAL HEALTH, CENTERS FOR DISEASE CONTROL AND PREVENTION, PUBLIC HEALTH SERVICE

STATEMENT OF THOMAS GARTHWAITE, M.D.

Dr. GARTHWAITE. Thank you, Mr. Chairman and members of the Committee. I am pleased to have this opportunity to update you on VA's Persian Gulf War-related programs.

VA continues to improve and expand our efforts to meet the needs of Persian Gulf veterans using a four-pronged approach, including medical care, research, compensation, and education. Each of these areas also involves significant efforts at outreach to Persian Gulf War veterans. The department is on record regarding its

accomplishments in each of these areas, and I would like to highlight our progress and note our recent initiatives and plans for the future in each area.

With regard to medical care, the VA's clinical response to Gulf War veterans includes completed registry examinations on 63,000 Persian Gulf War veterans, 1.8 million outpatient visits for 191,000 veterans, hospitalizations of 19,000 veterans, comprehensive evaluation at Persian Gulf War referral centers for 350 veterans, and counseling for 74,000 veterans at VA Readjustment Counseling VET centers.

The Presidential Advisory Committee agreed with the Institute of Medicine's conclusion that the clinical evaluation programs of the VA and Department of Defense are excellent for the evaluation and diagnosis of Gulf War veterans' illnesses. We believe, however, that we need to enhance the consistency of treatment of Persian Gulf War veterans and have implemented several initiatives aimed at improving care.

First, we are about to release a self-study program for physicians which will serve as a supplement to our current educational efforts.

Second, our customer feedback center is developing patient satisfaction surveys which will target Persian Gulf War veterans. The center has surveyed more than 200,000 veterans overall, and their data is a critical part of our expanding performance measurement system. We will focus this resource on Persian Gulf War veterans.

Third, we have developed quality indicators and performance standards for Persian Gulf War examinations. The results of these ongoing assessments will guide additional program changes in our educational efforts.

Fourth, I am pleased to announce that we are establishing service evaluation and action teams in each of our 22 Veterans Integrated Service Networks (VISINs). These teams are being formed to improve communication with veterans and to improve the responsiveness of VA health care delivery. These initial teams will be piloted with Persian Gulf veterans.

The teams will provide a mechanism for each network to continuously assess opportunities to enhance the effectiveness of VA clinical programs and respond to veterans' concerns. The teams, comprised of at least eight members representing a variety of disciplines and interests, including veterans, quality improvement specialists, patient representatives, and clinicians, will listen to and monitor trends in veterans' concerns about health care access, appropriateness of care and quality, and fulfillment of VA mandates. The information on reported concerns and recommendations for resolution will be referred to local medical center staff for action.

With regard to research, VA, as lead agent for federally sponsored Persian Gulf War research programs, has already laid the foundation for a comprehensive research plan. Together with the Persian Gulf War Veterans Coordinating Board's Research Working Group, VA has developed a structured research portfolio of more than 80 projects to address the currently recognized highest priority medical and scientific issues.

VA's own research program related to Persian Gulf War veterans' illnesses includes more than 30 individual projects being carried out nationwide by VA and university-affiliated investigators.

With the potential of exposure of some troops to low-dose sarin and cyclosarin as a result of the demolition at Khamisiyah, the Coordinating Board has revised its action plan. The modified plan will address possible long-term health consequences of low-level exposure to chemical warfare, neurotoxins, and mustard gas.

A recent review of the published scientific literature carried out by independent, nongovernment and government scientists suggests that readily identifiable long-term adverse health effects due to nerve agent exposures only occur in humans who show signs of acute toxicity or poisoning. However, research in this area is sparse and the absence of proof is not proof of absence.

In VA's judgment, this information does not preclude the possibility that clinically important adverse health effects occur in the setting of low-level neurotoxin exposures, especially if combined with other components or environmental stressors. The Coordinating Board has recommended that more research resources be allocated to address this question, and we strongly agree with this approach.

Based on the Coordinating Board's recommendation, the newest recommendations from the Presidential Advisory Committee have been already incorporated into the Coordinating Board's latest research working plan, including investigation of the potential chronic health effects of low-level chemical warfare agent exposures, expanded research on the physiologic effects of non-traumatic and traumatic stress and investigations of the effects of pyridostigmine bromide in combination with other exposure agents.

Funding for these new efforts will come from DOD's appropriation. And a copy of them has been provided to the Committee.

In concert with the Coordinating Board's recommendations, VA's research service is developing a strategic plan for an environmental health research agenda that specifically focuses on low-level exposures. To enhance the scientific dialogue amongst researchers, VA has organized a symposium on exposure to neurotoxins which bridges both military and civilian incidents and related research. At this symposium next month, a multidisciplinary group of experts from around the world will meet to focus on finding innovative solutions to these perplexing problems.

VA and DOD are partnering to expand their portfolios on stress-related research through the cooperative research program.

With regard to compensation, Mr. Chairman, as you know, we have a special provision of law governing compensation of undiagnosed illnesses. VA strongly supported Public Law 103-446 to allow VA to pay compensation to any Persian Gulf veteran with a chronic disability resulting from an undiagnosed illness.

In the regulation implementing the statute, we establish a 2-year presumptive period. There have been growing concerns that the 2-year presumptive period for undiagnosed illness may no longer be appropriate. Some veterans are reporting even now that they are experiencing, for the first time, unexplained illnesses that they believe are related to their service in the Persian Gulf.

Because of these concerns, the Secretary recommended to the President in early January that the issue of the presumptive period be revisited. On January 7, the President announced that he had approved this recommendation and asked Secretary Brown to report back to him in 60 days.

During the 60-day period, the Secretary is gathering as much information as possible from veterans, veterans' service organizations, members of Congress, and VA officials. The Secretary will provide advice to the President with regard to extending the presumptive period by March 8, 1997.

In the area of outreach and education, VA has a national training program for VA staff, including clinical meetings, satellite video conferences, teleconferences, printed fax sheets, and the planned self-study course I mentioned above. In addition, the Persian Gulf review is sent quarterly to a large mailing list, including all veterans on the Persian Gulf registry. The Persian Gulf hotline provides veterans and their families with a link to services and information available to Persian Gulf veterans.

Risk communication will be an emphasis in both VA's education and outreach programs. Coordination with DOD will occur to the Persian Gulf Coordinating Board's clinical working group.

VA vet centers, which were cited by the Presidential Advisory Committee as models for outreach, will be utilized in applying their time-proven strategies to risk communication and outreach to specific Persian Gulf populations.

In 1996, VA purchased satellite time to conduct one-on-one interviews with TV stations in top media markets for prime-time viewing. And we'll use this approach for future risk communication.

In response to the Presidential Advisory Committee interim report, VA hired a media marketing firm to distribute to print, radio, and television public service announcements and to provide follow-up reports on market penetration. This will be continued in 1997.

The Presidential Advisory Committee recommended that VA pay special attention to bilingual communications in areas with specific Latino populations. In 1996, VA published the first Spanish language version of "Federal Benefits for Veterans and Dependents." VA will also conduct Spanish language print, radio, and television interviews targeting Persian Gulf veterans.

The Presidential Advisory Committee also recommended special attention to women veterans. This has been a commitment of VA for many years. The VA women veterans' health programs have included Persian Gulf information in their national training program. Vet centers also include women veterans as a specific population for outreach related to readjustment counseling. This will continue.

VA is also conducting a thorough review of its reproductive health policies, including genetic counseling, as part of our eligibility reform package or as part of our writing regulations for the eligibility reform package passed by this body. The Presidential Advisory Committee recommendation will receive serious consideration as part of this review process.

In closing, I would like to thank the Presidential Advisory Committee for the thorough, in-depth review they provided to the complex issues of Persian Gulf veterans' illnesses and the thoughtful recommendations they have made to further address them. They

have provided a significant service to the veterans of that war and to those responsible for caring for them.

That concludes my statement, be happy to answer your questions.

[The prepared statement of Dr. Garthwaite appears on p. 329.]

The CHAIRMAN. Thank you, Doctor. We'll continue on through the panel and then get to the questions.

Dr. Joseph from Department of Defense.

Dr. JOSEPH. Thank you, Mr. Chairman. It's a pleasure to be here.

My statement is long and detailed. And, with your permission, I'd submit it in its entirety for the record and very, very briefly summarize and then come back to take your questions and comments.

The CHAIRMAN. Thank you, sir. We appreciate it.

STATEMENT OF STEPHEN C. JOSEPH, M.D., M.P.H.

Dr. JOSEPH. I am going to comment on four areas. The first is an overview, a history of the clinical and health research activities we have undertaken in the Department of Defense.

Second, I will say a few words about research, although I think Mr. Garthwaite has covered that ground very thoroughly.

Third, I want to make some comments about specific steps that we took on the medical side after learning of the Khamisiyah incident.

And then, finally, I'll say something about changes we have made in the Department's medical force protection and surveillance activities. I will go into more detail on that if you want, although it may be a little peripheral to this Committee's specific hearing today. But, the question keeps coming up, and I'm sure you heard it earlier today from the Presidential Advisory Committee: What have we learned from the Gulf experience that we'll put into place to protect future deployments?

We began in the Spring of 1994, several weeks after I was confirmed, to build a health and medical research activity. We first began with what has become known as our Comprehensive Clinical Evaluation Program.

At that time, the department had nothing in place. We began by working very closely with the model that the VA had begun developing somewhat earlier. Our first consideration was providing care to our people, taking care of the Persian Gulf veterans with symptoms and illnesses.

We set up a hotline, and began the CCEP program, again, with close coordination with the VA. That program has grown into a program that now has had 38,000 people registered, almost 30,000 receiving very sophisticated medical evaluations. And, as was previously said, all the groups that have looked externally at the VA and our own clinical programs—the Presidential Advisory Committee, the Institute of Medicine, et cetera—have given us very high marks for those activities.

We always say when we talk about them that these are not rigorous research programs. They were developed to take care of our people in the first instance. Second to use that experience, now a very large experience of some 60,000 people on the clinical side, to give us insights and signposts and guidelines in terms of the direc-

tions that we need to proceed in with regard to these symptoms and illnesses.

You've heard earlier from the PAC—and you will hear it wherever you look—at the VA, at the DOD's clinical programs, at the Institute of Medicine, there is a very strong unanimity of findings coming out of the clinical program. The most important one is that there is no evidence for a single or unique illness. There is not a Gulf War Syndrome. Rather what there is, is a broad and large collection of symptoms and illnesses due to a variety of causes that do not fit a case definition. They certainly do not fit a single cause or etiology as the explanation for most, or any great part, of the illnesses.

As we set up this clinical evaluation program, we also had an external independent, highly credible person—the dean, at the time, of the Tulane School of Public Health—look at our plans for the program, we wanted him to look over our shoulder.

At that same time we asked the Institute of Medicine of the National Academy of Sciences to set up a small committee—different from the larger research committee that they have set up to follow along with us—to look over our shoulder, critique our efforts, see whether they thought we were on the right road with our clinical evaluation protocol, itself, and also our conclusions. I believe that's probably been helpful to the VA as well.

This is ongoing. And it's especially important since Khamisiyah. As I said, we now have about 38,000 people on the registry.

With research, the only thing I would add to what Mr. Garthwaite has said is to stress again the importance of the Persian Gulf Veterans' Coordinating Board and the kind of research coordination that has enabled the agencies, principally VA and DOD but also HHS, to get a focus on where we're going and where the gaps are and to avoid duplication.

The DOD will spend \$27 million this year on Persian Gulf illnesses research, specifically focusing on the areas that Mr. Garthwaite mentioned.

With Khamisiyah, the rules changed. Our awareness changed, and our concerns about whether or not there was probable evidence of exposure to chemical weapons changed. We immediately took a series of medical steps to go back and look at those people we already evaluated in the CCEP; those who belonged to units that we judged to have been in the Khamisiyah area to see if, with that different knowledge through hindsight, we might find different patterns. Patterns that we had overlooked before.

To cut to the chase, in various other reviews and new listings of patients plus correlating CCEP participants with Khamisiyah, the only thing that I would say is: we see no pattern emerging that would show those people on our clinical register who were at Khamisiyah, or presumed to be at Khamisiyah, looking any differently in terms of their symptoms or their diagnosed illnesses.

Finally, about 2 years ago—and I wholeheartedly welcome the PAC statements on this issue—we began a change, in a very major way, the means by which we medically protect our people when they are going to deploy.

Should you be interested, I'll go through the list of things that we now do pre-deployment: better education, better health assess-

ments, personnel registers; during deployment: laboratories in the field for preventive medicine surveillance, environment surveillance, combat stress teams in the field; and then, post-deployment: health assessments, psychological questionnaire, and serum specimens in the bank, plus an enhanced level of electronic telemedicine capability to watch people's health during deployments.

We have implemented this during Bosnia. The Bosnia deployment is very different, in terms of force protection from a medical point of view, than previous deployments have been.

And, by the way, our experience in Bosnia on the illnesses side has been very, very good—really extraordinarily good. The illness rate in Bosnia has been lower than the average illness rates of troops in CONUS without deployment.

I'll stop there. I'll be happy to go back and pick up any of the areas you wish to talk about.

[The prepared statement of Dr. Joseph appears on p. 344.]

The CHAIRMAN. Thank you, sir. We may get into some of these others at a later hearing in more detail.

Dr. Rostker from the Department of Defense.

STATEMENT OF DR. BERNARD ROSTKER

Dr. ROSTKER. Mr. Chairman, thank you for the opportunity to appear before the Committee this afternoon. As you know, the Deputy Secretary of Defense, Dr. John White, appointed me Special Assistant for Gulf War Illnesses on November 12, 1996.

As a special assistant, my first priority is the health and welfare of our veterans and our troops. In this capacity, I serve as the DOD coordinator for all issues relating to Gulf War illnesses.

I see the Gulf War illnesses mission in three parts: first, to ensure that all who served in the Gulf receive appropriate medical care; second, that DOD does its part to ensure that we conduct a complete and thorough investigation to determine why so many of our veterans are ill; and, third, to apply our findings to future deployments.

The guidance from President Clinton is clear. He said, and I quote, "I want to assure all of you that we will leave no stone unturned in our efforts to investigate Gulf War illnesses and to provide our Gulf War veterans with the medical care they need. There are mysteries still unanswered, and we must do more." I make it my business every day to leave no stone unturned.

To carry out this important task entrusted to me by the Deputy Secretary, I have expanded by an order of magnitude the Department of Defense's investigative organization. The original team of 12 has been subsumed by a larger, more focused organization. And I have completely revamped the way we do business.

We are ensuring that we have the investigators and the analysts necessary to fully review current known episodes and I have the authority to search out and pursue reports of new incidences.

I have expanded into new areas to initiate a proactive risk communication strategy with two-way communications between the DOD and VA and the veterans as recommended by the President's Advisory Committee that you heard from earlier.

Today when a veteran calls our telephone hotline to offer information, the veteran receives a follow-up call and is interviewed by

a trained investigator, who ensures that information is incorporated into our case files. We are making significant strides in eliminating our backlog in all types of communication and in calling back to our veterans. These callbacks not only provide an in-depth debrief but for the future establish a dialogue between a single point of contact in my office and the reporting Gulf War veteran.

We are also placing e-mail capability on our GulfLINK Web site, which will enable us to be even more responsive to the concerns of our veterans and to more easily involve them in the investigative process. All of these actions contribute to increasing our understanding.

We also collaborate very closely with the veterans' service organizations to increase their knowledge about potential exposures during the Gulf War. For example, on December 11, 1996, we hosted the VSOs at a demonstration of the protective gear and chemical equipment used during the Gulf War, particularly the M-8 alarms, 256 test kits, and the Fox chemical reconnaissance vehicles. They indicated to us that they appreciated the opportunity to become more familiar with the equipment that has often been described in the media and was the subject of congressional debate.

Additionally, on January 30, last week, we hosted a group from the VSOs to tour our new office complex and callback operations, which allowed them the opportunity to meet with our people and to focus on our operations.

We have also formalized the structure for our incidence investigation. We are now preparing a series of case narratives that summarize what we know about such incidents as Khamisiyah, the Marine breaching operation, operational logs, Fox alarms, pyridostigmine bromide, and every other issue under investigation. And I'd like to add that within the next week, we expect to publish our first case narrative on Khamisiyah.

These narratives will be a status report to the American people of what we knew, when we knew it, and what actions we're taking. As we prepare these narratives, they not only show us what we know, but they also, and perhaps most importantly, reveal what we don't know, allowing us to focus on our investigative actions.

The first case narrative is Khamisiyah, and it will be available in the near future, as I indicated.

We expect this process to facilitate the dialogue between us and our veterans and their families. This is the start of a process, not the end of a process. We expect that veterans will contact us with more information so we can flush out the record and provide the best information possible.

The expansion of my office has also allowed us to broaden our focus on other possible causes of Gulf War Illness. For example, we are beginning to devote more resources to the investigation of possible environmental hazards such as pesticides and insecticides as we reconstruct the events that occurred during the Gulf War, we will look closely at our doctrine, policies, and procedures.

We must be completely open minded in our analysis and make the requisite changes based upon the lessons that we learn.

We are building on the major health programs initiated by DOD to care for those still on active duty or otherwise eligible for DOD

care. The Comprehensive Clinical Evaluation Program that Dr. Joseph spoke about was established to provide in depth evaluations of health concerns of Gulf veterans who are on active duty or serve in the National Guard or Reserve.

We have asked all personnel who want to be evaluated to contact the program to schedule an appointment for medical evaluation. And this is very important. Sometimes there's some confusion about who was at Khamisiyah or not at Khamisiyah. Anyone who has a concern about their health who served in the Gulf needs to contact DOD or the veterans—Department of Veterans Affairs.

To date, more than 38,000 Gulf War veterans have registered. And of those, 30,000 have been—requested medical examinations. The Department of Veterans Affairs has completed in excess of 63,000 examinations.

As you know, last month I withdrew the DOD staff paper published on GULFLINKS which discounted low level exposure as the cause for Gulf Illness. In doing this, I noted that the PAC had concluded that current scientific evidence does not support a causal link between low level chemical exposure and undiagnosed Gulf Illnesses.

However, the PAC also recommended additional research is warranted. We concur in this assessment and plan to fund the appropriate research. I appropriate this subject with a completely open mind. Our research agenda is clear evidence of this. And again, we will coordinate this research program with HHS and VA through the established Persian Gulf Veterans' Advisory Board.

The CHAIRMAN. Do you have very long to go?

Dr. ROSTKER. About another 2 or 3 minutes. Want me to stop?

The CHAIRMAN. I wish you would, sir.

Dr. ROSTKER. Okay.

The CHAIRMAN. We've got seven, eight more witnesses to go and two more panels. We appreciate it very much. Thank you.

If you could maybe just briefly summarize what you have left there, and perhaps members—

Dr. ROSTKER. Well, let me just say in conclusion that we are wholeheartedly committed to finding out everything we can about the factors that impact on Gulf Illness. This is absolutely necessary, not only because it's right for our veterans, but also because it's imperative for the future safety of our troops.

Thank you, sir.

The CHAIRMAN. Thank you, sir. And your entire statement will be put into the record.

Dr. ROSTKER. Thank you, sir.

[The prepared statement of Dr. Rostker appears on p. 356.]

The CHAIRMAN. Dr. Jackson.

STATEMENT OF RICHARD J. JACKSON, M.D., M.P.H., DIRECTOR, NATIONAL CENTER FOR ENVIRONMENTAL HEALTH, CENTERS FOR DISEASE CONTROL AND PREVENTION

Dr. JACKSON. Good afternoon. Mr. Chairman, thank you for the invitation to be here.

I'm Dr. Richard Jackson. I'm Director of the National Center for Environmental Health, the Centers for Disease Control. To my

right is Dr. Stewart Nightengale, Associate Commissioner at the Food and Drug Administration.

We're here to comment on the Presidential Advisory Committee recommendations, and I have extensive comments on CDC's involvement in my written testimony. I'll just summarize our comments here. Dr. Nightengale will respond on the FDA comments as well.

We would like to commend the Presidential Advisory Committee for its comprehensive review of the complex issues involving examining the health consequences. We take note of the PAC's finding that many veterans were clearly experiencing medical difficulties connected with their service in the Gulf War.

In fact, CDC's—HHS's own studies have reached a similar conclusion. The causes of these illnesses need to be thoroughly investigated. However, answering such questions is exceedingly complex, and we may never be able to determine the precise causation of illness in all Persian Gulf Veterans.

That is why it's important for us to examine future actions that can be taken to control or prevent health problems among our military personnel. In this regard, it's essential that HHS continue its close collaboration with DOD and VA.

This collaboration has resulted in several well designed investigation of health outcomes among Persian Gulf vets.

We concur with the Presidential Committee on the importance of health communication in—health education in dealing with Gulf War veterans. Several centers at CDC, NIOSH, also at the Agency For Toxic Substances, have a lot of expertise in this area. As recommended by the PAC, we were very willing to provide that help and those services.

The PAC also emphasized the important role of public advisory groups. HHS has had a lot of experience with this. In fact, the IOWA study that CDC was the lead on, we worked with both a veterans' advisory group as well as a science advisory group.

The public advisory groups often provide a lot of critical information and advice—the use of language, whatever, in the design of these studies. And they also help to increase the public awareness of both the strengths and the limitations of epidemiologic studies and hopefully will help in public acceptance of the study results.

I'd like to make a strong point about the importance of peer review, and that whatever results come out have to be reviewed by arm's length third party reviewers in order to stand that kind of scrutiny.

The advisory committee recommended several priority research areas. For example: the long term effects of low level exposure to chemical agents, the long term effects of stress, the long term effects of carcinogens and mutagens, and the long term effects of the interactions between drugs such as pyridostigmine bromide and other agents.

Obviously we concur with those recommendations.

HHS is in full agreement with the committee on anticipating post-conflict health concerns associated with military employment. Now the ongoing studies of Persian Gulf veterans will contribute to our understanding of the effects of military service.

However, most of these studies are limited by their retrospective nature. By looking back over time, we're very aware of the difficulties in trying to address concerns that develop months and years after deployment.

In most instances, investigators are called in only after an environmental health problem is suspected. And as a result, base line data on the health of the military personnel is often lacking.

It's essential that we take a more forward looking approach to evaluating veterans' health concerns. And such an approach would consist of a) gathering baseline data on the health of military personnel; b) surveillance systems for adverse health outcomes; c) developing better troop locator methods, knowing where people are serving; and identifying risk factors for stress related conditions.

And this would include—and this is very important—collection and storage of baseline and post-deployment serum samples, blood samples.

We would like to commend the PAC for its emphasis on stress related disorders. As the report points out, stress is known to affect the brain, the immune system, heart, other endocrine immune responses. And further study of the impact of stress on physical as well as psychological functioning can only benefit our efforts in helping the veterans.

The Presidential Advisory Committee recommends that the Government consider methods for routinely sampling military populations regarding reproductive health so that an appropriate baseline exists. In particular, the report suggests that DOD work with CDC's Center For Health Statistics on our national survey for family growth.

This is a survey of women of childbearing age to look at reproductive health, family planning, maternal and child health, sexually transmitted diseases, HIV infection. And obviously, CDC would be pleased to provide the technical consultation to do so.

Finally, the PAC commented on FDA's Interim Final Rule permitting waiver of informed consent for use of unapproved products in a military emergency. The committee expressed concern about the time FDA has taken to reopen the rule making process.

The FDA intends to reopen the rule making process and will solicit public comment in line with the committee's report. This public comment will be directed towards whether FDA should finalize the rule, modify it, or eliminate it completely. And FDA will also continue to work, as it has over the last several years, with DOD and others on this.

I will not comment on the IOM report because of time. But in summary, DOD and VA have the primary responsibility for protecting the health of military personnel, and HHS will strongly and does strongly support the findings of the Presidential Commission.

To the extent possible, we will work closely with these two agencies on this. We owe a debt of gratitude to the veterans and to all men and women in military service.

And I will be glad to answer any questions that the committee may have.

[The prepared statement of Dr. Jackson appears on p. 362.]

The CHAIRMAN. Thank you, Doctor. And thank you, gentlemen. If you would respond to the questions, we'll move right along. Mr. Evans.

Mr. EVANS. Thank you, Mr. Chairman.

Dr. Garthwaite, you indicated that there are some 80 studies in progress at this point, research studies, by the VA. Can you submit to us kind of a summary of each one of those studies?

Dr. GARTHWAITE. We will be more than happy to, sir.

[The information follows:]



A Working Plan For Research on Persian Gulf Veterans' Illnesses

Persian Gulf Veterans Coordinating Board



First Revision

November 1996

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PREFACE

Persian Gulf War veterans report a variety of symptoms and illnesses that may have been caused by their military service. Although the Departments of Veterans Affairs (VA) and Defense (DoD) have taken important steps to ensure that these veterans have access to quality medical care, there is an urgent need to increase understanding of the nature and extent of these illnesses, and their potential connection to service in the Persian Gulf.

The overwhelming majority of Persian Gulf veterans who have come to VA or DoD for medical care have been found to have common conditions and have received appropriate treatment for their problems. However, similar to the general civilian population, some veterans have symptoms that are difficult to explain using current diagnostic criteria for illnesses. A critical unresolved issue is whether they are experiencing these symptoms at a higher rate than comparable non-Persian Gulf war veterans. In addition, many veterans have questioned whether the illnesses that are common and diagnosable are etiologically linked to their service in the Persian Gulf conflict. While many medical questions have been answered with existing knowledge of the Persian Gulf veterans' experience, others require scientific research.

The VA, DoD, Department of Health and Human Services (HHS), and Environmental Protection Agency (EPA), through the Persian Gulf Veterans Coordinating Board (PGVCB), have led the way in the conduct of research on Persian Gulf veterans' illnesses. In 1995 it was apparent that the scope of the research issues necessitated the development of a working plan to help the Persian Gulf Veterans Coordinating Board coordinate federally-sponsored research in a way that all the relevant research issues would be targeted but unnecessary duplication would be avoided. This document is the first revision of the original 1995 *A Working Plan for Research on Persian Gulf Veterans' Illnesses* (PGVCB, 1995). Because research, by its nature, often leads to unexpected findings, as well as refinement in thinking about specific topics, the original plan was designed to be flexible and evolve over time. New research findings in the past year and other information that has come to our attention, as well as the initiation of new research, have led to the need for a revision of the *Working Plan*. It is anticipated that the *Working Plan* will undergo further revisions in the future.

The original research plan and subsequent revisions attempt to balance the need for specific, targeted research directions, with the awareness that successful research, fostered by sound research questions, arises from the minds of independent scientists in research laboratories. Therefore, the *Working Plan* sets the broad research areas in which it is believed investment will most likely bring new and useful knowledge.

Although the *Working Plan* is primarily intended to guide federal decision makers in establishing research priorities, it is also meant to provide information to members of Congress, the scientific community, the public and, importantly, the veterans of the Persian Gulf conflict, about the manner in which the federal government is carrying out this important research.

In the interest of completeness, this revision of the *Working Plan* includes material from the original 1995 *Working Plan*. New research information is woven into the main body of this revised *Working Plan*.

It is important to note that the *Working Plan* is an essential component of research, and that research is only one element of a broader strategy aimed at addressing the health problems and concerns of Persian Gulf veterans and their families. These elements include:

- **MEDICAL CARE**
Providing appropriate medical care has been a top priority of VA and DoD. The two departments have acted aggressively to ensure the delivery of high quality medical care to Persian Gulf veterans.
- **RESEARCH**
Research, which is the subject of the present document, is indispensable to the improvement of medical care for Persian Gulf veterans, the institution of appropriate interventions, and to the formation of a firm basis for compensation.
- **COMPENSATION**
VA and DoD continue to work diligently to ensure prompt and appropriate compensation of Persian Gulf veterans disabled by their military service.
- **EDUCATION AND OUTREACH**
Persian Gulf veterans and their health care providers must have access to the latest information on medical care, compensation, and research. This information will enable veterans to make sound judgments about their own health status, and to know how and where they can seek assistance. It will also enable physicians, and other health care providers, to provide state-of-the art diagnoses and treatment to veterans.

Finally, to help ensure that the US Government is doing everything possible to determine the causes and provide care to those who are ill, the President established a Presidential Advisory Committee on Gulf War Veterans' Illnesses that began its work in August 1995. This Advisory Committee is reviewing and providing recommendations on the full range of US Government activities on this important issue. Its final report is expected in December, 1996.

Through the continued implementation of the *Working Plan*, in conjunction with the other components of the overall strategy, it is hoped that confident, reliable answers to the concerns of Persian Gulf veterans can be obtained as quickly as possible and with maximal efficiency.

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health
Department of Veterans Affairs

1. EXECUTIVE SUMMARY

Since veterans returning from the Persian Gulf first started to report symptoms and illnesses in late 1991, a significant number of clinical evaluation and research activities have been undertaken. In 1995 the magnitude of the research effort required implementation of a comprehensive plan. This resulted in publication by the Persian Gulf Veterans Coordinating Board (PGVCB) of *A Working Plan for Research on Persian Gulf Veterans' Illnesses* (PGVCB, 1995) on August 5, 1995. Since that time the number of research programs investigating Persian Gulf veterans' illnesses has increased substantially. Some research programs have begun to produce results. New information about potential exposures to chemical weapons has become available. These changes in the context within which research is conducted have necessitated this revision of the 1995 *Working Plan*. As with the original document, the current plan maps out the course by which the following goals can be pursued:

- Establish the nature and prevalence of symptoms, diagnosable illnesses, and unexplained conditions among Persian Gulf veterans in comparison to appropriate control groups;
- Identify the possible risk factors for any illnesses, beyond those expected to occur, among Persian Gulf veterans;
- Identify appropriate diagnostic tools, treatment methods, and prevention strategies for any excess illness conditions found among Persian Gulf veterans.

The *Working Plan* is coordinated by the Department of Veterans Affairs (VA) in conjunction with the Persian Gulf Veterans Coordinating Board. The research conducted under the aegis of this plan is executed by various departments and agencies, including VA, DoD, and HHS. The Research Working Group (RWG) of the PGVCB is the primary research coordinator and is charged with assessing the state and direction of research; identifying gaps in factual knowledge and conceptual understanding; identifying testable hypotheses; recommending research directions for participating agencies; reviewing research concepts as they are developed; collecting and disseminating scientifically peer-reviewed research information; and ensuring that all research conducted under the umbrella of the RWG undergoes appropriate scientific peer-review, and that the results of peer-review lead to appropriate actions by the sponsoring agencies.

Establishment of the prevalence of symptoms and illnesses in comparison with appropriate control populations is an essential base upon which additional research depends. If Persian Gulf veterans are experiencing symptoms and illnesses that are in excess of expectations for such a population, further research into risk factors can then be approached by separating the overall investigation into two categories: analysis of health outcomes and analysis of exposures. These analyses need to be conducted in a manner that defines the association between exposures and outcomes.

Based on the findings of three scientific panels -- the Defense Science Board Task Force (DSB, 1994); the NIH Technology Assessment Workshop (NIH, 1994); and the Institute of Medicine (IOM, 1995) -- and other current information, exposures to psychological war

stressors, *Leishmania tropica* (*L. tropica*), petroleum products, insecticides and insect repellents [possibly in combination with pyridostigmine bromide (PB)], are important to consider if any excess illnesses are found. Vaccines, chemical agents resistant coating (CARC) paint, depleted uranium (DU) and smoke from oil well fires have been considered by the scientific panels as unlikely sources of Persian Gulf veterans' illnesses.

A key component of the 1995 *Working Plan* was an assessment of current knowledge and research on Persian Gulf veterans' illnesses. This assessment, along with guidance from the aforementioned scientific panels, led to the identification of the following areas of inquiry for which significant gaps in knowledge existed at that time:

- Information on the prevalence of symptoms, illnesses, and/or diseases within other coalition forces;
- Information on the prevalence of symptoms, illnesses, and/or diseases within indigenous populations within the Persian Gulf area including Saudi Arabia and Kuwait;
- Information on the prevalence of adverse reproductive outcomes among Persian Gulf veterans and their spouses;
- Simple and sensitive tests for *L. tropica* infection that could lead to quantification of the prevalence of *L. tropica* infection among Persian Gulf veterans; and
- Information on the long-term, cause-specific mortality among Persian Gulf veterans.

In June of 1995 DOD issued a Broad Agency Announcement (BAA) soliciting research proposals to investigate Persian Gulf veterans' illnesses. Proposals were sought from federal and non-federal scientists who were encouraged to broadly direct their efforts to epidemiology, clinical research, and research on pyridostigmine bromide. The solicitation was given additional focus by the research gaps identified in the 1995 *Working Plan*. In June 1996, DoD and VA announced the award of the first 12 of 15 new research grants as an outcome of the original BAA. These were selected on the basis of scientific merit by an independent scientific review panel, and on program relevancy derived from the list of research gaps. These new projects, and other research initiatives in 1995/1996, address most of the gaps identified in the 1995 *Working Plan*.

Events in 1995/1996, including the addition of new research, results of ongoing research, and new information about exposures during the Persian Gulf War, form the basis of a new assessment of knowledge and research.

In the 1995 *Working Plan* it was stated that lacking confirmatory evidence of exposure to chemical or biological weapons, research on chemical and biological weapons should not be undertaken. Since then, there have been reports of potential exposures resulting from allied bombing of two Iraqi chemical weapons facilities, and the destruction by US ground forces of a munitions bunker and storage pit that United Nations inspection teams have concluded contained sarin and cyclosarin. This new information raises concern about chemical weapons exposure, and leads to recommendations for more research on the long-term effects of low-level exposures to chemical agents, including basic research and epidemiologic investigations.

Epidemiologic studies are now beginning to provide information about the prevalence of self-reported symptoms, illnesses, and self-reported exposures among Persian Gulf veterans, and their spouses and children. Furthermore, clinical epidemiology and basic research are also beginning to yield results relevant to the determination of potential pathologies and their risk factors underlying the symptoms.

Findings from some of these studies indicate the following:

- Some groups of Persian Gulf veterans have self-reported an excess of symptoms in comparison with non-deployed veterans of the same era (Kaiser et al, 1995; CDC, 1995). A connection between symptoms and a specific disease pathology or pathologies has not been identified.
- Based on VA and DoD mortality studies to date (Kang and Bullman, 1996; Writer et al, 1996), there does not appear to be an excess of disease-specific deaths in Persian Gulf veterans when compared to veterans of the same era.
- A Navy study of hospitalizations (Gray and Coate, 1996a,b) indicates that, at least among active duty personnel, the rate of hospitalizations of Persian Gulf veterans does not exceed their non-deployed counterparts. This suggests that Persian Gulf veterans are not experiencing an excess of illnesses of a severity that would lead to hospitalization.
- One focused study of a small cohort of Persian Gulf veterans (Penman et al, 1996) and one study of military hospitalizations (Cowan et al, 1995) did not uncover an excess of birth defects among their offspring. Several ongoing and new epidemiologic studies are investigating pregnancy and birth outcomes. Results from these studies will begin to be available in 1997.
- A DoD study (US Army, 1995) of the interaction of PB, DEET, and permethrin in high dose, orally-exposed rats provides evidence in an animal model for synergistic effects of these compounds. Synergism is also suggested in a study of neurotoxicity in chickens at lower, though still acutely toxic, doses (Abou-Donia et al, 1996). This research suggests the need for further exploration of the potential interactive effects of these compounds at doses of greater relevance to humans. Research currently being conducted by DoD and VA will attempt to further address issues of PB and other compounds that could have interacted with it.
- A single study focusing on high-level central nervous system processing (Goldstein et al, 1996) found no clinically significant neuropsychological differences between a symptomatic, self-selected group of Persian Gulf veterans and a control group, with psychological stress accounting for the small deficits that were detected.
- A study focusing on the peripheral nervous system (Jamal et al, 1996) in 14 self-selected Persian Gulf veterans found small, but significant differences in 3 of 22 tests of peripheral nerve function related to large fiber peripheral nerve function and thinly myelinated small fiber function.

The epidemiologic investigations cited above were generally conducted in narrowly defined cohorts not necessarily representing the entire population of Persian Gulf veterans. Therefore, the ability to generalize beyond those studies to larger populations of Persian Gulf veterans is

limited. However, results from ongoing epidemiological studies, when completed and combined with these findings, will facilitate broader generalizations.

In addition to new research findings and new research initiatives in the United States, the US Government is coordinating its research effort with Great Britain and Canada, each of whom participated in the Persian Gulf War as coalition partners. VA scientists are also actively collaborating with researchers in Denmark and Japan. Denmark participated in the Persian Gulf War as a coalition partner. The collaboration with Japanese scientists involves follow-up research on individuals exposed to sarin in the Tokyo subway terrorist incident in 1995.

Emerging findings from ongoing research in the past year, and new factual information on the potential for chemical weapons exposure in southern Iraq in 1991 lead to the following specific, near-term recommendations for additional research:

- Follow-up of the mortality experience of Persian Gulf veterans, encompassing cause-specific mortality, at appropriate future time-points;
- More longitudinal follow-up studies of the health of Persian Gulf veterans, including those with illnesses that are difficult to diagnose;
- Critical peer-review of models used to predict exposure concentrations of environmental pollution (such as the Kuwait oil well fires) and chemical warfare agents (such as the demolition of weapons storage sites at Khamisiyah in March, 1991 and aerial bombing of chemical weapons facilities during the air war);
- Assessment of the potential for clinical investigations of the health status of the service members in the vicinity of Khamisiyah when weapons bunker 73 and the storage pit were detonated in March, 1991. If deemed possible, such clinical investigations should be carried out.

Additional research on health-related issues arising from the Persian Gulf experience but with potential for more general applicability to future conflicts is also recommended, including:

- Investigation of the risk factors for the development of stress-related disorders including, but not limited to, post-traumatic stress disorder (PTSD);
- Investigation of the risk factors responsible for the observed excess mortality due to external causes (e.g., motor vehicle accidents) in veterans of all wars and conflicts;
- Exploration of the development of practical, sensitive, and specific biomarkers of exposure to chemical agents, including organophosphate nerve agents and vesicants such as sulfur mustard.
- Toxicological and, where feasible, epidemiological research on the potential for long-term health effects resulting from low-level, sub-clinical exposures to chemical agents, particularly organophosphate agents such as sarin;
- Development of a strategic plan for research into the potential long-term health consequences of exposure to low-levels of chemical warfare agents;
- If a simple, sensitive and specific, as well as economic, test for *L. tropica* infection becomes available, seroepidemiologic studies may be undertaken in Persian Gulf veterans. Indeed, when feasible and practical, sera of veterans should be stored in expectation of the possibility for such studies. Despite the declining importance of *L.*

tropica as a risk factor in Persian Gulf veterans, continued research on tests for *L. tropica* infection are valuable for potential future deployments.

It is further recommended that a contextual framework for the results of completed and ongoing studies be provided to develop approaches for the collective interpretation of research results. A meeting of researchers should be organized to provide such a framework.

Because of the changing nature of scientific research, and the acquisition of new factual information, this plan will likely undergo additional revisions in the future.

SECTION 1**EXECUTIVE SUMMARY**

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2. INTRODUCTION**2.1 BACKGROUND**

A wide variety of symptoms and illnesses began to be reported by veterans returning from the Persian Gulf conflict in late 1991. The initial response to this problem appropriately involved descriptive studies including:

- Clinical evaluations;
- Disease outbreak and cluster investigations;
- Population health surveillance;
- Initial exposure inventory and assessment;
- Troop location.

The response included establishing the Department of Veterans Affairs (VA) Persian Gulf Registry Health Examination Program ("Persian Gulf Registry") and Persian Gulf Referral Centers, and the Department of Defense (DoD) Comprehensive Clinical Evaluation Program (CCEP). These major clinical undertakings resulted in appropriate medical care and allowed the systematic collection of clinical, and other descriptive data, regarding the health of Persian Gulf veterans that would aid in treatment of veterans and active duty service members.

As of October 1996, over 62,000 Persian Gulf veterans had completed the VA registry examination and had their examination. Of veterans in the registry with one or more symptoms, 77% received medical diagnoses from VA clinicians. The DoD CCEP reveals a similar pattern of findings among the more than 18,500 participants who had completed the examination as of the same time (DoD, 1996)

Overall, the VA Persian Gulf Registry and the CCEP have identified a wide spectrum of overlapping symptoms involving multiple organ systems. As of May 1996, the most commonly reported symptoms from the VA Persian Gulf Registry include:

<u>SYMPTOM</u>	<u>FREQUENCY</u>
Fatigue	20%
Skin rash	18%
Headache	18%
Muscle/Joint pain	17%
Memory loss	14%
Shortness of breath	8%
Sleep disturbances	6%
Diarrhea and other GI symptoms	5%
Chest Pain	4%

In the initial stages of the search for a cause of these symptomatic conditions, attention was brought to the multitude of environmental, occupational, and biological exposures that may have been experienced by many of the troops. When combined with the unique conditions of a rapid, large-scale deployment, it was evident that a quantitative understanding of the nature of these exposures would be needed along with better understanding of the illnesses.

2.2 THE ROLE OF RESEARCH

The need to establish whether there is a link between medical conditions and service in the Persian Gulf resulted in the initiation of a broad-based research program. The *Working Plan for research* is intended to help coordinate and focus the research efforts sponsored by the federal government in a coherent and cost-effective manner. This document presents an approach to answering questions about the nature of illnesses experienced by Persian Gulf veterans. This research is intended to pursue the following goals:

- Establish the nature and prevalence of symptoms, diagnosable diseases, and other conditions in Persian Gulf veterans in comparison to appropriate control populations;
- Identify possible risk factors for any excess morbidity or mortality among Persian Gulf veterans; and,
- Identify appropriate diagnostic tools, treatment methods, and prevention/intervention strategies for conditions found among Persian Gulf veterans.

The research necessary to achieve these goals includes basic research, which is necessary to establish the knowledge base upon which clinical and epidemiological research are built. Where appropriate and feasible, research will address family members of veterans, as well as veterans per se.

2.3 RESEARCH MANAGEMENT AND COORDINATION

Research on Persian Gulf veterans' illnesses is complex, involving a number of different approaches and outcomes. The federal research enterprise involves scientists conducting research sponsored by VA, DoD, and HHS. Each of these Departments have distinct, though complementary, capabilities and capacities for conducting and sponsoring research on Persian Gulf veterans health issues. Each Department has its own appropriation for extramural and intramural general biomedical research programs. Extramural funds generally support research efforts at non-federal institutions such as universities. Intramural funds generally support in-house research. However, at most VA medical centers, intramural research is conducted in conjunction with academic medical center affiliates. The Department of Defense also has a separate item in its appropriation for DoD/VA collaborative research on health problems shared by veterans and active duty service members alike.

The biomedical research programs in VA, DoD, and HHS have well established management structures for science policy formulation and the solicitation, scientific peer review, and funding of both extramural and intramural programs. The coordination and management of research on Persian Gulf veterans' illnesses has required the establishment of an overall research policy framework linking each Department's research management hierarchy. The linkage is provided through the Research Working Group of the Persian Gulf Veteran's Coordinating Board [composed of representatives from VA, DoD, HHS, and the Environmental Protection Agency (EPA)]. The Research Working Group is charged with assessing the state and direction

of research; identifying gaps in factual knowledge and conceptual understanding; identifying testable hypotheses; recommending research directions for participating agencies; reviewing research concepts as they are developed; collecting and disseminating scientifically peer-reviewed research information; insuring that the appropriate research is done without unnecessary duplication; and insuring that federally sponsored research undergoes appropriate peer review and oversight. As an operational policy, the Research Working Group works through the line management authority each department maintains over its intramural scientists, scientific program managers (responsible for extramural research), and their budgets.

Each Department engaged in research on Persian Gulf veterans' illnesses emphasizes the need for ongoing prospective and retrospective peer review of research. Because of the urgency of the health concerns of Persian Gulf veterans and their families, as well as the diverse nature of the reported illnesses, review and oversight of research is essential. VA, DoD and HHS have established several oversight mechanisms to capture the diverse nature of the overall effort; some oversight mechanisms are broad-based, encompassing all research issues, whereas others are more focused on individual research projects and programs.

2.4 PURPOSE OF THE WORKING PLAN

This plan:

- Identifies the knowledge needed to achieve the above-stated goals;
- Identifies the knowledge that is currently available or will be obtained from ongoing research at some time in the foreseeable future;
- Identifies the research areas that need to be covered to close the gap between what is known and what is needed.

This plan is a dynamic working document that will undergo periodic modifications as new knowledge emerges and as research findings improve the understanding of Persian Gulf veterans' illnesses. The current document is the first revision of the original 1995 *Working Plan* and replaces the original document.

2.5 ORGANIZATION OF THIS DOCUMENT

To establish a knowledge baseline for the *Working Plan*, it is valuable to first examine the assessments of Persian Gulf veterans' health issues carried out by various expert panels. These include the NIH Technology Assessment Conference on Persian Gulf Veterans Experience and Health, the National Academy of Science/Institute of Medicine/Medical Follow-Up Agency panel on the Health Consequences of Service During the Persian Gulf War, the Defense Science Board Task Force on Gulf War Health Effects, and the Presidential Advisory Committee on Gulf War Veterans' Illnesses. Section 3 provides a brief overview of the assessments conducted by these panels. In the period since reports from the aforementioned panels were published there have been research findings that must be integrated with previous assessments. Section 4 is an assessment of research needs factoring in prior assessments, contemporary research findings, and the current research portfolio. Recommendations for additional research resulting from this assessment include research that is specific to the health

SECTION 2**INTRODUCTION**

experience of Persian Gulf veterans, as well as research that has long-term impact for future deployments and military conflicts.

The Persian Gulf Veterans' Illnesses Research Database is provided for reference in the Appendix. To the best of our knowledge, it contains all relevant and credible research on Persian Gulf veterans' illnesses sponsored by the federal government and, along with research information from the non-federal research sector, is the basis for the determination of future research directions. It also includes 15 new research projects awarded by DoD as a result of a Broad Agency Announcement (BAA) in 1995 soliciting research from federal and non-federal investigators. The selection of research projects was based on scientific merit and program relevancy. Program relevancy was determined in part by the research gaps identified in the 1995 *Working Plan*. A more detailed summary of federally sponsored research in 1995 can be found in the *Annual Report to Congress: Federally Sponsored Research on Persian Gulf Veterans' Illnesses, 1995* (PGVCB, 1996a).

3. GENERAL FINDINGS FROM PANEL ASSESSMENTS

In late 1993, as information from initial descriptive studies became available and plans for future studies were being developed, it was evident that an assessment of the data and investigational activities was in order. Assessment activities were undertaken by the Defense Science Board (DSB), the National Institutes of Health (NIH), the National Academy of Sciences/Institute of Medicine/Medical Follow-up Agency (IOM), and most recently by the Presidential Advisory Committee on Gulf War Veterans' Illnesses.

3.1 DEFENSE SCIENCE BOARD

DoD commissioned the Defense Science Board Task Force on Gulf War Health Effects. The Task Force was specifically charged with reviewing all available intelligence and reports of detection of chemical agents and toxins during Operations Desert Shield/Desert Storm (ODS/DS) and the post-conflict period. In addition, the Task Force was to review scientific and medical evidence relating the possibility of low-level exposure to chemical and biological warfare (CBW) agents to potential long term health effects. A similar review was conducted for possible industrial pollutants and other potential causes of unexplained illnesses. The DSB Task Force met six times between November 1993, and March 1994. In the course of its work, the Task Force heard presentations from a wide range of scientific and medical experts from within and outside DoD. The Task Force published its final report in June 1994 (DSB, 1994). The members of the DSB Task Force reached consensus on a number of key points, including:

1. There is "... no scientific or medical evidence that either chemical or biological warfare was deployed at any level against us, nor that there were any exposures of US service members to chemical or biological warfare agents in Kuwait or Saudi Arabia."
2. There is "...no persuasive evidence that any of the proposed etiologies caused chronic illness on a significant scale in the absence of acute injury at initial exposure."
3. There is insufficient epidemiological evidence at this time "...to support the concept of any coherent 'syndrome'."

Because many veterans report symptoms similar to Chronic Fatigue Syndrome (CFS), the DSB Task Force felt it would be advantageous to coordinate further research on veterans' illness in this category with ongoing studies of CFS in the civilian population.

In light of new knowledge indicating there may have been release of chemical warfare agents in March, 1991 as a result of demolitions of weapons bunkers near Khamisiyah, Iraq (see Section 4.1.5), the first point is drawn into question. However, there is still no direct scientific or medical evidence of exposure.

3.2 NIH TECHNOLOGY ASSESSMENT WORKSHOP

The NIH Technology Assessment Workshop, "Persian Gulf Experience and Health", was convened April 27-29, 1994, and was co-sponsored by VA, DoD, HHS, and the Environmental Protection Agency (EPA). The expert panel addressed four issues: (1) the prevalence of unexplained illnesses; (2) whether a case definition could be developed; (3) potential etiologies of unexplained illnesses; and (4) recommendations for future research.

The NIH panel found that insufficient epidemiological data existed to determine whether there was an increased prevalence of illnesses among veterans due to service in the Persian Gulf War (NIH, 1994). The panel also concluded that while there are several complexes or patterns of symptoms unexplained by established disease categories, it would be premature to establish a case definition. The panel could not identify a single or multiple etiology for unexplained illnesses, but noted the appearance in some Persian Gulf veterans of a newly identified form of leishmaniasis (viscerotropic leishmaniasis). The panel also suggested that the unique stresses of the Persian Gulf experience may have led to a previously unrecognized manifestation of post-traumatic stress disorder (PTSD).

3.3 NATIONAL ACADEMY OF SCIENCES/INSTITUTE OF MEDICINE/ MEDICAL FOLLOW-UP AGENCY

As directed by P.L. 102-585, VA and DoD entered into a contract with the National Academy of Sciences/Institute of Medicine/Medical Follow-up Agency (IOM) to "...review existing scientific, medical, and other information on the health consequences of military service in the Persian Gulf theater of operations during the Persian Gulf War." In contrast to the NIH Workshop, this effort was designed to conduct an assessment in greater depth, over a three year time period.

On January 4, 1995, the IOM issued a report "Health Consequences of Service During the Persian Gulf War: Initial Findings and Recommendations for Action" (IOM, 1995). In general the IOM panel endorsed the DSB and NIH findings of no single disease entity with no single etiology. The panel also strongly emphasized the importance of population-based studies. The panel found no evidence that either chemical or biological warfare (CBW) agents were used against coalition troops during the Persian Gulf conflict and, as a consequence, recommended that this not be a factor in considerations of the causes of Persian Gulf veterans' illnesses.

The IOM panel completed its deliberations in the Summer of 1996 and issued its final report in September, 1996 (IOM, 1996). In this report (which stands as a separate document from the January, 1995 report) the panel stated that it could find no scientific evidence to date demonstrating adverse health consequences associated with service in the Persian Gulf War beyond the few documented cases of leishmaniasis, combat-related or injury-related mortality or morbidity, and increased risk of psychiatric sequelae of deployment. The panel went on to state that there is a strong likelihood that no single hypothesis could account for all of these, whether or not the illnesses result from service in the Persian Gulf War. Finally, the panel observed that after previous wars and conflicts, a proportion of military service personnel and veterans have had medical complaints of varying degrees of severity that are not explainable based on identifiable health hazards or physical illnesses. This observation echoes work by Hyams et al (1996) tracing such a phenomenon back at least to the Civil War.

3.4 PRESIDENTIAL ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES (PAC)

The President established this advisory committee by Executive Order on May 26, 1995. The 12 member committee is composed of scientists, health care professionals, veterans, and policy experts. The Committee is charged with reviewing and providing recommendations on the full range of government activities relating to Persian Gulf veterans' illnesses.

The Committee released an interim report in February 1996 (PAC, 1996a). Although the Interim Report stated that VA, DoD, and HHS research programs are generally well designed and should lead to answers, it also had several recommendations. The Committee's recommendations covered issues such as peer review, coordination of agency research activities, the use of public advisory committees and the availability of information on troop exposure. In response to the Interim Report, the agencies developed a coordinated plan of action (PGVCB, 1996b) that responds to the Advisory Committee's interim recommendations. The final report of the Committee is scheduled for release in December, 1996.

The Committee made no findings about specific illnesses or exposures in the Interim Report. However, at a public meeting of the PAC in Chicago, Illinois, on July 8-9, 1996 (PAC, 1996b), Committee Staff presented to the Committee their assessment of major potential risk factors. A meeting in Cincinnati, Ohio, on July 23, 1996 (PAC, 1996c) was devoted specifically to stress as a risk factor, and a meeting in Denver, Colorado, on August 6, 1996 (PAC, 1996d) revisited depleted uranium and oil well fires as risk factors. As in the IOM Final Report (IOM, 1996), Committee Staff were unable to identify any single risk factor, other than stress, that could explain a large number of illnesses reported by Persian Gulf veterans. It should be emphasized that these conclusions were those of Committee Staff and do not necessarily represent the final findings of the Committee proper.

As will be seen from the discussion of various exposures and health outcomes in the next section, the views of the Persian Gulf Veterans Coordinating Board Research Working Group do not diverge from those of the various review and assessment panels. As new information has become available, however, we continue to build on these reviews and assessments. Nevertheless, the door must not be closed to considerations of other exposures and outcomes since new research findings from ongoing studies have the potential for affecting these conclusions.

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4. FRAMING THE PROBLEM

In the 1995 *Working Plan* a set of research questions were developed based on the NIH, DSB, and IOM (in the initial report of January, 1995) findings and recommendations. Each question was followed by an evaluation of the degree to which then current research was addressing these questions, followed by a set of recommendations for additional research. In this revised version the formulation of these questions is restated. Current, on-going (or recently completed) research projects addressing these questions are then presented along with relevant findings. This is followed by an updated list of research needs for the question of concern.

As with the 1995 *Working Plan*, the most important question about the health of Persian Gulf veterans is:

Are Persian Gulf veterans experiencing a greater prevalence of symptoms and illnesses in comparison with an appropriate control population?

From the answer to this question springs virtually all subsequent questions that may be addressed through research. For example, if there is an increased prevalence of certain symptoms among Persian Gulf veterans in comparison to controls, then what disease or diseases are being manifested by these symptoms, and what connection with service in the Persian Gulf might exist? Therefore, the first research question that needs addressing is:

RESEARCH QUESTION 1

What is the prevalence of symptoms/illnesses in the Persian Gulf veterans population? How does this prevalence compare to that in an appropriate control group?

In the past year two studies (CDC, 1995; Kaiser et al, 1995) have demonstrated that while objective measures remained consistent between study and comparison groups, in select cohorts of Persian Gulf veterans there is a greater prevalence of symptoms (similar in type to the VA Persian Gulf Registry and the DoD CCEP) when compared to non-deployed veterans. Because of the limited sizes of these cohorts generalizability is difficult. In addition, Coate et al (1995) have shown that active duty service members who served in the Persian Gulf had no more hospital admissions than those who were not deployed to the Persian Gulf. This suggests that as a group Persian Gulf veterans are not experiencing a greater prevalence of major illnesses.

Research Underway

PROJECTS VA-2, 4, 5, 6, 18; DoD-1A,B,E,F, 30, 39; HHS-1, 2 (NOTE: Project numbers associated with current research refer to projects contained in the Appendix.): Components of each of these projects are designed to estimate the prevalence of symptoms in Persian Gulf veterans and compare this prevalence to control groups of non-deployed veterans.

Additional Research Needed

- The ongoing epidemiological studies will determine the need for additional studies.

If ongoing studies continue to demonstrate an increased prevalence of self-reported symptoms and illnesses, then the secondary questions regarding disease entity or entities must continue to be vigorously pursued.

Casting the problem of Persian Gulf veterans' illnesses into an exposure-outcome framework helps to isolate two interconnected questions: (1) what was the nature and extent of *possible exposures* experienced by veterans while in the Persian Gulf?, and (2) what adverse health outcomes, *if any*, have occurred among Persian Gulf veterans, beyond what would be normally expected in such a large population? These two questions lead to a third, namely: (3) is there a relationship, or set of relationships, between exposure to the complex environment of the Persian Gulf War theater and any *excess* health outcomes that is consistent with established biological and toxicological principles, and with epidemiological data? This last question requires identification and quantitation of both exposures and health outcomes. Investigation of exposures can lead to hypotheses about expected health outcomes based on the nature and extent of the exposures, and investigations of health outcomes can lead to hypotheses about exposures.

Because of the inherent logical value of separating the problem into exposure and health outcome, the *Working Plan* separates research oriented primarily toward exposure from research directed primarily at evaluating health outcomes.

4.1 EXPOSURES

While deployed in the Persian Gulf theater, troops may have experienced a variety of exposures, both natural and environmental/occupational in origin, to a varied extent. Potential exposures of concern that have been cited are: infectious agents (such as *Leishmania tropica*); smoke from oil well fires; exposure to other petroleum products and their combustion products; other occupational exposures such as pesticides, chemical agents resistant coating (CARC) paint; CBW agents; vaccines; pyridostigmine bromide (PB); and psychophysiological stressors of war. The number of troops and the amount of exposure to any one, or combination of, these exposures is not known at this time.

TABLE 2
Summary of Potential Exposures of Concern for Health Outcomes

Exposures	Scientific Review Panel		
	DSB	NIH	IOM
Infectious Agents	+	+	+
Smoke from Oil Well Fires/Oil Spills	-	-	-
Other Petroleum Products	*	+	+
Other Occupational Exposures	*	+	*
CBW Agents	-	*	-
Vaccines	-	-	+
Pyridostigmine	*	+	+
War Stressors	+	+	+

- + Recommended for further review and research
- Unlikely to be of primary concern for long-term health consequences
- * The exposure was either considered by the panel, but not highlighted, or was not considered by the panel.

Table 2 summarizes the findings of the DSB, NIH, and IOM panels with respect to these exposures. All three panels agreed that psychophysiological stressors of war and infectious agents required further review or research. Further research into exposure to other petroleum products and pyridostigmine bromide was recommended by IOM and NIH, but DSB made no specific recommendation. All three panels also agreed that it is unlikely that oil well fires or vaccines caused illnesses in Persian Gulf veterans.

With respect to CBW exposure, the NIH panel initially deferred making a finding about CBW until the DSB completed its deliberations. Both the DSB and the IOM (in its January, 1995 initial report) subsequently reported lack of confirmation of exposure to CBW agents. Further research related to these potential exposures was not recommended by DSB or IOM in its initial report (IOM, 1995). Recent findings that exposure of US service members to chemical warfare agents may have occurred near Khamisiyah, Iraq in March, 1991 have significantly altered this view (see Section 4.1.5 below).

Below is a discussion of each of the exposures. For each exposure a general background is provided along with any new research data that have become available. This is followed by specific research questions with statements of current research and any additional studies that are needed. Studies that pace other studies (i.e., studies that must be complete before others can proceed) or studies that are paced by other studies are identified.

4.1.1 Infectious Agents

Coalition troops were exposed to a number of infectious agents present in the Persian Gulf area. The most notable of these is the parasite *Leishmania tropica*. To date only 12 cases of viscerotropic and 20 cases of cutaneous leishmaniasis have been diagnosed among Persian Gulf veterans (DoD, 1996), clearly suggesting minimal exposure. Diagnosis of viscerotropic leishmaniasis, however, is difficult because there is no accurate serological test for the presence of the parasite. Thus, actual exposure and infection rates are difficult to obtain. After the passage of five years and the absence of a significant number of cases of either cutaneous or viscerotropic leishmaniasis, the likelihood of *L. tropica* as an important risk factor for widely reported illnesses has diminished.

Other infectious agents were also present in the Persian Gulf area that could cause chronic diseases, including schistosomiasis, Q fever and brucellosis (DeFraités et al, 1992; Ferrante MA et al, 1993). Only a few cases of these diseases have been diagnosed among the US troops who served in the Persian Gulf, and there is no indication that such infections are widespread or are related to unexplained illnesses (Hyams et al. 1995).

Acute infectious disease outcomes typical of cramped military living conditions, such as dysentery and respiratory tract infection, were actually lower than expected during the Persian Gulf conflict (DSB, 1994; Richards et al, 1993a,b; Richards et al, 1991). Exposure to other infectious agents such as mycoplasmas, bacteria, viruses, and fungi probably occurred but there is not a strong case from any clinical evaluations that supports these organisms as possible etiologic factors. However, because of the possible role for *Leishmania* in unexplained illnesses, all three scientific review panels recommended further research to develop a simple, sensitive and specific diagnostic test.

RESEARCH QUESTION 2

What was the overall exposure of troops to *Leishmania tropica*?

If this question is to be ultimately addressed, a highly sensitive, yet specific diagnostic screening test must be developed. Only then would it be possible to address the research question. Progress has been reported by Dillon et al (1994) who have developed a recombinant antigen that has been characterized and detects immune response in patients with viscerotropic leishmaniasis. Specificity and sensitivity of this test are currently unknown. Because of the potential for development of specific and sensitive serological tests, serum samples collected as a part of population-based epidemiological studies of Persian Gulf veterans should be banked, when feasible and practical, to facilitate testing once an appropriate test is available.

Despite the diminishing likelihood of *L. tropica* as a risk factor, it is worthwhile to continue work in this area because it is relevant for future deployments.

Research Underway

PROJECT DoD-8A,B, 38: These three projects involve development of a reliable skin test (screening for past infection) and serologic assay (testing for active infections).

Additional Research Needed

- Development and testing of diagnostic tests determine all further leishmaniasis research directed at this research question.

4.1.2 Smoke from Oil Well Fires and Oil Spills

The US Army Environmental Hygiene Agency has characterized the carcinogenic and non-carcinogenic risk from exposure to smoke from the Kuwait oil well fires (USAEHA, 1994). This risk assessment demonstrates minimal potential carcinogenic risk. The bulk of non-cancer risk is from volatile organic compounds, but this risk is judged to be low. These risk assessments, however, are only valid for personnel located at sites where environmental measurements were made. In DoD-18 an oil well plume model is being developed using monitoring data as input. The model output, when expressed in a format compatible with the military geographic information system (GIS) for troop unit location (PROJECT VA-3), should provide an approximation of the oil well plume exposure as a function of time for troop units. This model will prove to be very valuable for future spatial analyses requiring exposure information. DoD and VA need to ensure that this model has been adequately peer reviewed. Based on previous recommendations of review panels and the lack of any new information that alters the findings, further oil well smoke exposure research beyond the USAEHA model, and its application to risk assessment, is not being pursued at this time.

4.1.3 Other Petroleum Products

During the war, some troops may have been exposed to petroleum vapors, solvents and combustion products. Kerosene, diesel and leaded gasoline from local sources were sometimes used for heating, ground spraying to suppress sand dust, and incinerating both trash and human waste. As a result, some troops could have been exposed to benzene, toluene, ethylbenzene, xylene and other petroleum combustion products. Elevated levels of sulfur dioxide, nitrogen dioxide, nitric acid, acidic sulfates, carbon monoxide, lead, respirable particulates and other pollutants may be expected in tents using unvented heaters burning gasoline and diesel fuels. There were no measurements of any of these pollutants in tents. Concern that this type of exposure was high enough for significant health consequences prompted both the NIH and IOM panels to recommend a simulation of exposure in tents heated by diesel fuel with composition similar to that used in the Persian Gulf area. The IOM noted the presence of elevated blood lead levels derived from autopsy specimens from seven service members who died in the Persian Gulf theater may have been related to contamination from specimen storage containers (IOM, 1996). The pharmacokinetics of lead make meaningful follow-up difficult at best (Legett RW, 1993). In an ongoing clinical study, investigators have not found any evidence of current elevated blood lead levels among Persian Gulf veterans (Roswell, 1995).

RESEARCH QUESTION 3

What were the exposure concentrations to various petroleum products, and their combustion products, in typical usage during the Persian Gulf conflict?

In one attempt to address this question investigators at NIH (HHS-3), in conjunction with USAEHA, have measured urinary metabolites of polycyclic aromatic hydrocarbons (PAH), PAH-DNA adducts, and genetic polymorphisms in 62 soldiers in June 1991, prior to deployment to Kuwait, eight weeks into their deployment, and after their return to Germany from Kuwait in October 1991. Results indicate that soldiers may not have experienced significant exposures to PAHs associated with the incomplete combustion of petroleum while stationed in Kuwait.

Research Underway

PROJECT DoD-2, 34: A component of DoD-2 involves the simulation of exposures to petroleum and petroleum combustion products in enclosed spaces. DoD-34 involves direct simulations of exposures in tents characterizing the nature and concentrations of petroleum combustion products.

PROJECT DoD-19: This research attempts to expand the modeling of DoD-18 to characterize all potential exposures in Kuwait and Saudi Arabia.

Additional Research Needed

- DoD and VA need to ensure that this and other exposure models have been adequately peer reviewed.

4.1.4 Other Occupational Exposures

Other potential environmental hazards, including pesticides, microwaves, chemical agent resistant coating (CARC) paint fumes, depleted uranium (DU) and cleaning solvents were present in the Persian Gulf theater. Some of these chemicals, such as CARC paint and DU, are not likely to be a primary cause of unexplained illnesses among Persian Gulf veterans because only small numbers of troops were exposed (NIH, 1994). A full assessment of risk from exposure to these chemicals cannot be made in the absence of accurate exposure data.

RESEARCH QUESTION 4

What was the extent of exposure to specific occupational/environmental hazards known to be common in the Persian Gulf veteran's experience? Was this exposure different from that of an appropriate control group?

Research Underway

PROJECT DoD-2: In addition to the petroleum and combustion products simulations listed above, simulations of exposure to other chemicals will also be conducted.

PROJECT DoD-19: This research attempts to expand the risk assessment modeling of DoD-18 to characterize all potential exposures in Kuwait and Saudi Arabia.

PROJECTS VA-2, 4A, 5A, 6-Core, 13; DoD-1A,D,E, 30, 39; HHS-1,2: Components of each of these epidemiology studies will collect self-reported exposure data using a variety of survey instruments. Results of exposure simulations may help to estimate the level of self-reported exposures.

Additional Research Needed

- The ongoing studies will determine the need for additional studies.

4.1.5 Chemical and Biological Warfare Agents

Both the DSB and IOM panels concluded that reports of the possible use of CBW agents cannot be confirmed and that bombing of Iraqi storage areas did not cause CBW agent exposure. While awaiting assessment of the DSB, the NIH panel drew no conclusions about the presence or absence of CBW. The IOM panel in their initial report (IOM, 1995) stated that claims of exposure to chemical or biological warfare agents should not be made or given credence in the absence of reliable substantiating data. Despite this, the DoD established the Persian Gulf Investigations Team (PGIT) to investigate, among other things, reports of CBW exposure provided to a 1-800 hotline.

In June 1996, DoD announced that a munitions bunker (#73) in Khamisiyah, Iraq, destroyed by US demolition teams on March 4, 1991, probably contained the chemical agents sarin and cyclosarin. On March 10 a pit containing sarin was also destroyed by US troops. Because of this, it is likely that some US military personnel in the vicinity were exposed to chemical warfare agents. In addition, chemical weapons storage sites at Muhammadiyat, and Al Muthanna, Iraq (northwest of Baghdad), were destroyed by allied bombing at the beginning of the Persian Gulf War, creating a potential risk of chemical agent exposure downwind of these sites.

Testimony provided to the Presidential Advisory Committee meeting on June 8-9, 1996, (PAC, 1996b) by representatives of the United Nations Commission charged with the accounting and destruction of weapons of mass destruction in Iraq, and by the US Central Intelligence

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Agency (CIA), suggest that Khamisiyah was the only site in southern Iraq and Kuwait at which chemical weapons were present. If this is so, the incident at Khamisiyah may be entirely isolated. However, the report itself raises a sufficient degree of uncertainty to conclude that potential exposures to chemical warfare agents should no longer be excluded from consideration as a valid subject of research.

Two exposure issues immediately arise. The first one relates to the potential exposure of troops present at the Khamisiyah site at the time of demolition, and the potential exposure of troops as a result of the bombing of the Muhammadiyat and Al Muthanna weapons depots. The second relates to the more general issue of chemical agent exposure.

RESEARCH QUESTION 5

What were the potential exposures of troops to organophosphate nerve agent and/or sulfur mustard as a result of allied bombing at Muhammadiyat and Al Muthanna, or the demolition of a weapons bunker at Khamisiyah

In testimony at the June 8-9, 1996, PAC meeting (PAC, 1996b), contractors to the CIA presented the results of model calculations predicting ground level concentration of chemical agent as a function of distance and direction away from the March 4 detonation site at Khamisiyah (CIA, 1996). The model predicts that at the location of the troops chemical agent concentration should have been below any level expected to produce even mild acute effects. The CIA also modeled the plumes resulting from the bombings at Muhammadiyat and Al Muthanna. The model predicts levels well below what would be expected to cause even mild acute effects for troops located 400 - 500 km south of the sites. At the time of this writing, CIA has not completed its model calculations for ground level sarin concentrations resulting from the March 10 pit detonation. At the moment, model predictions provide some reassurance. However, model applications to these situations need to undergo scrutiny by outside experts.

Many of the ongoing epidemiological investigations collect self-reports on chemical agent exposure. Although these data may have value in assessing risk factors, the potential for report bias is always present. In the absence of actual exposure data acquired at the site of detonation, only model calculations can presently be relied upon. Exposure biomarkers for chemical agents have the potential for determining exposure on an individual basis after an actual exposure has ceased. However, there are no known exposure biomarkers for either organophosphate nerve agents or vesicants, and even if there were they would probably be of little value since over five years have elapsed since the Persian Gulf War.

Research Underway

PROJECTS VA-2, 4A, 5A, 6-Core, 13; DoD-1A,D,E, 30, 39; HHS-1,2: Components of each of these epidemiology studies are collecting self-reported exposure data using a variety of survey instruments. Although these studies are not directly focused on troops present at Khamisiyah, self-reporting and input from the troop unit locator database may provide some information on potential exposure, albeit not necessarily more detailed than

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time and location of individual units. Results of further exposure simulations may help to estimate the intensity of self-reported exposures.

Additional Research Needed

- Existing plume model calculations should be critically reviewed.
- Exploration of the development of practical, sensitive, and specific biomarkers of exposure to chemical agents including organophosphate nerve agents and vesicants such as sulfur mustard.

The second exposure question can be stated as:

RESEARCH QUESTION 6

What was the extent of exposure to chemical agent, other than at Khamisiyah, Iraq, in the Persian Gulf as a function of space and time?

Despite the evidence indicating the very low probability of widespread chemical warfare agent exposures in the Persian Gulf, concern has been elevated by the bombings of Muhammadiyat and Al Muthanna, and the event at Khamisiyah in March 1991. Consequently there is a need to evaluate the potential for exposure of troops to chemical agent at other times and locations. In the absence of quantitative data, virtually all exposure information will be derived from self-reports, and thus, subject to bias. Although exposure biomarkers are probably of little use in the context of any chemical warfare agent exposure in the Persian Gulf, the need for reliable objective exposure markers is evident.

Research Underway

PROJECTS VA-2, 4A, 5A, 6-Core, 13; DoD-1A,D,E, 30, 39; HHS-1,2: Components of each of these epidemiology studies are collecting self-reported exposure data using a variety of survey instruments.

Additional Research Needed

- Exploration of the development of practical, sensitive, and specific biomarkers of exposure to chemical agents, including organophosphate nerve agents and vesicants such as sulfur mustard.

With respect to biological warfare agents, there continues to be no evidence of use by Iraq, or exposure of troops during or after the Persian Gulf War. These determinations were confirmed by both UN and CIA officials at the July 1996 meeting of the PAC (PAC, 1996b). The absence of any reports of infection from anthrax or acute illnesses from botulinum toxin in the Persian Gulf theater lends further credence to this conclusion.

4.1.6 Vaccines

Troops who served in the Persian Gulf conflict were vaccinated without significant side-effects against common infectious diseases with vaccines frequently used in the general population. In addition, approximately 150,000 troops received at least one dose of anthrax vaccine and about 8,000 received at least one dose of botulinum toxoid. Both vaccines have been used for many years without adverse effects. All three review panels stated that no long-term adverse effects have been documented or would be expected. Further study of the potential adverse effects of vaccines in this population is not recommended by any of the three panels, nor is it endorsed in this plan.

4.1.7 Pyridostigmine Bromide

Pyridostigmine bromide (PB) is a cholinesterase (ChE) inhibitor that was supplied to troops for use as prophylaxis against exposure to nerve agents. PB was distributed to troops in blister packs of 21 tablets of 30 mg each. PB tablets were taken on order when it was believed a gas attack was imminent. The recommended dosage was one tablet every 8 hours. PB has been in use for decades (at much higher dosages) in the treatment of patients with myasthenia gravis. Short-term side effects are well known -- e.g., nausea, vomiting, diarrhea, abdominal cramps, increased salivation, miosis, headache and dizziness. There have been no documented long-term side effects of this drug. Exposure information is provided solely from self-report of veterans.

RESEARCH QUESTION 7

What was the prevalence of PB use among Persian Gulf troops?

Research Underway

PROJECTS VA-2, 4A, 5A, 6-Core; DoD-1A,D,E, 30, 39; HHS-1,2: Components of each of these epidemiological studies collect self-reported PB use data for Persian Gulf veterans using a variety of instruments.

Additional Research Needed

- The ongoing epidemiological studies will determine the need for additional studies.

4.1.8 Psychophysiological Stressors of War

Psychiatric morbidity among US troops deployed to the Persian Gulf area was predicted even though the war was of short duration, resulted in relatively low numbers of casualties, and positive support for the war prevailed at home. Persian Gulf veterans were exposed to many psychophysiological stressors besides direct combat, such as sudden mobilization for military service (especially among members of reserve and National Guard units), exposure to dramatic oil well fires, the constant threat of CBW agents, and fear of combat in general. A wide range of somatic and psychological responses could be expected from individuals deployed to the Persian Gulf area from stress associated with deployment (Wolfe et al, 1993; Ursano and Norwood,

1996). All three review panels recognized the possible role of psychophysiological stressors associated with deployment and the possibility of a psychophysiological response among Persian Gulf veterans. All three panels, and the Committee Staff of the PAC (PAC, 1996d), have encouraged further scientific research in this area.

RESEARCH QUESTION 8

What was the prevalence of various psychophysiological stressors among Persian Gulf veterans? Is the prevalence different from that of an appropriate comparison population?

Research Underway

PROJECTS VA-2, 4A, 5A, 6-Core, 7, 12; DoD-1A,D,E, 4, 5, 6A,B, 30, 39, 40; HHS-1, 2: Components of these studies are acquiring self-reported data on exposure to psychophysiological stressors among Persian Gulf veterans and appropriate control populations. DoD-30 and DoD-39 will add specific information about the stressors in female Persian Gulf veterans and in British Persian Gulf veterans respectively.

Additional Research Needed

- More research is needed on the role of a variety of stressors as risk factors for later development of stress-related disorders, including, but not limited to, PTSD.

4.1.9 Troop Locations

One of the most important variables in considering any exposure is determining the location in the Persian Gulf War theater of individual service members as a function of time. Information about troop location down to the individual service member was not recorded. However, unit diaries (where a unit consists of approximately 100 troops) were maintained on a daily basis for all units. Matches between units and individuals can be made. The US Army and Joint Services Environmental Support Staff Group (JESSG) is currently in the process of computerizing troop unit locations (PROJECT VA-3). Computerized records were completed for the Air Force, Navy, and Marines at the end of 1995. Eighty percent of the records were completed for the Army at the end of 1995. The remaining records will be complete by late 1996. Because the results from this project are needed for several epidemiological investigations, this project is of vital importance.

4.2 HEALTH OUTCOMES

The most frequently cited health outcomes and concerns related to service in the Persian Gulf are:

- Non-specific symptoms/symptom complexes;
- Immune function abnormality/autoimmune disease;

- Reproductive health outcomes;
- Genitourinary disorders;
- Pulmonary function abnormality;
- Neuropsychological/neurological outcomes;
- Psychological/psychiatric outcomes;
- Infection;
- Cancer/neoplastic disease;
- Mortality outcomes.

Table 3 provides a summary of the DSB, NIH, and IOM findings on health outcomes. When the potential for long-term health consequences was considered, all panels agreed that further research into psychological outcomes, non-specific symptom complexes, and leishmaniasis was needed. In addition, the IOM and NIH panels recommended research on neurological and neuropsychological outcomes. The remaining potential health outcomes were each considered significant by only one panel. In such cases, though, the other two panels had no comment. This latter observation must be treated with caution since concern about some potential health outcomes have been raised only recently.

TABLE 3
Summary of Reported Health Outcomes

Health Outcomes	Scientific Review Panels		
	DSB	NIH	IOM
Non-specific Symptoms/ Symptom Complexes**	+	+	+
Immune Function Abnormality	*	*	*
Reproductive Health Outcomes	*	*	+
Genitourinary Disorders	*	*	+
Pulmonary Function Abnormality	*	+	*
Neuropsychological - Neurological Outcomes	*	+	+
Psychological/psychiatric Outcomes	+	+	+
Infection	+	+	+
Cancer/Neoplastic Disease	*	*	*
Mortality Outcomes	*	*	+

+ Recommended for further review and research

- Unlikely to be of primary concern for long-term health consequences

* The outcome was either considered by the panel, but not highlighted, or was not considered by the panel.

** Including Chronic Fatigue Syndrome (CFS), chemical sensitivities, and fibromyalgia

Below, each health outcome is considered individually. For each health outcome a general background is provided. This is followed by specific research questions with statements of current research and any additional studies that are needed.

4.2.1 Non-Specific Symptoms/Symptom Complexes

Within any population the size of the Persian Gulf veterans cohort (approximately 700,000 who served in Operations Desert Shield/Desert Storm), individuals will experience various health complaints and may become ill at some time. Some of these symptoms and illnesses may not be fully explained despite intensive clinical work-ups. On the other hand, it is possible that some of these symptoms may fall into unique complexes that can be categorized.

RESEARCH QUESTION 9

Are Persian Gulf veterans more likely than an appropriate comparison group to experience non-specific symptoms and symptom complexes?

Recently, investigators have demonstrated in 1498 Seabees (Construction Battalion personnel) an increase of symptoms among deployed versus non-deployed Seabees with no physical correlates (Kaiser et al, 1995). Investigators with the CDC and the State of Pennsylvania have also demonstrated an increase of symptoms within groups of deployed versus non-deployed Air National Guardsmen in Pennsylvania (CDC, 1995). Symptom patterns in the latter study bear a similarity to Chronic Fatigue Syndrome, however the severity of symptoms is milder than in Chronic Fatigue Syndrome.

Research Underway

PROJECTS VA-2, 4A, 5A, 6-Core, 18; DoD-1A,E, 30, 39, 40; HHS-1,2: Components of each of these studies are acquiring data on self-reported non-specific symptoms. Some (see below) are also investigating the presence of identifiable symptom complexes. DoD-30 and DoD-39 are collecting data in cohorts of women and British Persian Gulf veterans respectively. DoD-40 is not designed to address prevalence of illness, but is a longitudinal study of PTSD in Persian Gulf veterans.

PROJECT VA-2; HHS-2: These studies include a physical examination to validate the self-reported symptoms on a subset of the survey study population.

PROJECTS VA-4A, 4B, 5B, 5C, 6B; DoD-31, 32, 39; HHS-2: Components of these studies are directed specifically at hypotheses that unexplained illnesses are associated with symptom complexes identified as CFS, fibromyalgia, or other symptom-based syndromes. At a minimum they should provide information on the prevalence of these complexes.

Additional Research Needed

- Most of the ongoing epidemiological studies are cross-sectional in nature. There needs to be additional emphasis placed on longitudinal studies focusing on the health of Persian Gulf veterans.

4.2.2 Immune Function

Suggestions have been made that some Persian Gulf veterans have experienced an alteration in immune function or host defense. One hypothesis is that aromatic hydrocarbons, and other related compounds, may cause suppression of immune function through activation of the aromatic hydrocarbon receptor (AhR) on cell lymphocytes and, subsequently, induction of lymphocyte death, thereby suppressing immune function.

RESEARCH QUESTION 10

Do Persian Gulf veterans have a greater prevalence of altered immune function or host defense when compared with an appropriate control group?

Research Underway

PROJECTS VA-4A, 5A, 6-Core, 17; DoD-37, 48: Virtually all of these studies are collecting standard, clinical immune function data. VA-4A is conducting research on a model for the upregulation of the AhR. VA-5A is studying peripheral blood polymorphonuclear leukocytes for chemokine expression. VA-5A is also examining blood mononuclear cells for reactivation for EBV, CMV, herpes 6 and herpes 7. DoD-37 is investigating alterations of immune response in male and female rats following PB, DEET, and permethrin exposures, alone or in combination. This project is also conducting *in-vitro* investigations of the effects of exposure to these compounds on human lymphocyte immune response. DoD-48 is investigating the frequency of chromosome 7 inversions in blood specimens of symptomatic and asymptomatic Persian Gulf veterans.

Additional Needed Studies

- The ongoing studies will determine the need for additional studies.

4.2.3 Reproductive Health Outcomes

Adverse pregnancy and birth outcomes associated with Persian Gulf area deployment have been a major concern among the Persian Gulf veterans. The IOM panel has recommended that reproductive outcomes be included among the health endpoints in surveillance programs and that population-based studies of these outcomes be conducted.

RESEARCH QUESTION 11

Is there a greater prevalence of birth defects in the offspring of Persian Gulf veterans than in an appropriate control population?

An investigation was conducted by the Mississippi Department of Health in collaboration with CDC of birth defects in children of Persian Gulf veterans from a Mississippi national guard unit (Penman, 1996). Birth defects were identified and the diagnoses verified. The results were compared to expected values. The number of birth defects was not higher than expected for that population although the study had inadequate statistical power to detect any differences in specific defects. Investigators at the Naval Health Research Center in San Diego have examined military hospital discharge records for births to spouses of deployed active duty service members and among deployed active duty women (Cowan et al, 1995). They found that when these women were compared to their non-deployed counterparts, no difference in birth defects between the two groups could be found. Data have been collected to determine the prevalence of Goldenhar Syndrome among infants of the same populations (Araneta, 1996).

Current Research

PROJECTS VA-2, DoD-1D,E, 30; HHS-1: Components of each of these epidemiological studies are identifying through survey questionnaires birth defects in offspring of Persian Gulf veterans and in those of appropriate controls.

PROJECT DoD-1G: This study will match Persian Gulf veterans and non-deployed era veterans with birth defects registries in 7 states to determine if the overall and diagnostic-specific prevalence of congenital abnormalities differs among Persian Gulf veterans, non-deployed era veterans and the general population.

PROJECT DoD-35: This is a feasibility study to determine if all children born to Persian Gulf veterans residing in California can be identified and if congenital anomalies in the first year of life can be identified.

Additional Research Needed

- The ongoing epidemiological studies will determine the need for future studies.

RESEARCH QUESTION 12

Have Persian Gulf veterans experienced lower reproductive success than an appropriate control population?

Research Underway

PROJECTS VA-2; DoD-1D,E,C, 30; HHS-1: Different components of each of these studies will investigate the prevalence of failure to conceive, miscarriage, spontaneous abortion, and stillbirth and compare the prevalence to that of an appropriate control population.

Additional Research Needed

- The ongoing epidemiological studies will determine the need for future studies.

4.2.4 Genitourinary Disorders

There have been individual reports of sexual dysfunction among Persian Gulf veterans, including infrequent reports of these phenomena in both the VA and DoD surveillance systems.

RESEARCH QUESTION 13

Is the prevalence of sexual dysfunction greater among Persian Gulf veterans than among an appropriate comparison population?

Research Underway

PROJECTS VA-2; DoD-1A, 1E, 30, 39; HHS-1: Components of these epidemiology studies will determine, through survey questionnaires, the prevalence of various manifestations of sexual dysfunction in Persian Gulf veterans (or in the veterans' partners) compared to that in an appropriate comparison population.

PROJECT DoD-44: This project will investigate immunologic mechanisms by which a women could develop an allergic reaction to her sexual partner's semen.

Additional Research Needed

- The ongoing epidemiological studies will determine the need for additional studies.

4.2.5 Pulmonary Function Abnormality

Some troops may have been exposed to potentially significant amounts of petroleum vapors, combustion products and sand dust. Depending on exposure concentration and absorbed dose, repeated and chronic exposure to these chemicals and substances could possibly result in

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impairment of pulmonary function. The NIH panel recommended a retrospective cohort study to investigate pulmonary function related to petroleum combustion products.

RESEARCH QUESTION 14

Do Persian Gulf veterans report more pulmonary symptoms or diagnoses than persons in appropriate control populations?

DoD investigators have found that while active duty deployed Persian Gulf veterans from a Seabee unit self-reported more respiratory symptoms, their objective pulmonary function tests did not differ from a non-deployed control group (Kaiser et al, 1995).

Research Underway

PROJECTS VA-2, 4A, 5A, 6-Core; DoD-1A, 1E, 30, 39; HHS-1: Components of these studies are using surveys to ascertain the self-reported prevalence of pulmonary symptoms/diagnoses (e.g., asthma, bronchitis, etc.) among Persian Gulf veterans compared to an appropriate control population. Exposure-outcome relationships will be explored.

Additional Research Needed

- The ongoing epidemiological and other studies will determine what, if any, additional studies are required.

RESEARCH QUESTION 15

Do Persian Gulf veterans have a smaller baseline lung function in comparison to an appropriate control group? Do Persian Gulf veterans have a greater degree of non-specific airway reactivity in comparison to an appropriate control group?

Research Underway

PROJECTS VA-4D; DoD-1A, 39: These projects are conducting cohort studies to determine whether there are any differences in pulmonary function and, to a lesser extent, airways reactivity between Persian Gulf veterans and Persian Gulf era veterans. As mentioned previously, DoD investigators have found that although active duty deployed Persian Gulf veterans from a Seabee unit self-reported more respiratory symptoms, their objective pulmonary function tests did not differ from a non-deployed control group (Kaiser et al, 1995).

PROJECTS DoD-2, 3: Components of these projects involve exposures of laboratory animals to a variety of inhaled pollutants. Pathophysiologic effects that may provide information on potential human health outcomes will be studied.

Additional Research Needed

- The ongoing studies will determine the need for additional studies.

4.2.6 Neuropsychological and Neurological Outcomes

The subjective reports of generalized fatigue and cognitive impairment in Persian Gulf veterans enrolled in the VA and DoD registries suggest the possibility of a neuropsychological component to their health problems. The self-reported exposures of troops to chemicals with potential neurological effects (such as PB, many of the pesticides, the insect repellent DEET, the insecticide permethrin, and potentially organophosphate chemical weapons) also suggest that neurological and neuropsychological outcomes may be important.

The simultaneous or sequential administration of certain compounds (for example, PB and the insect repellent DEET) conceivably could interact to produce an additive or synergistic neurologic effect. However, previous research has indicated that PB does not persist in the body and, therefore, is unlikely to cause any long-term effects (Breyer-Pfaff et al, 1985). Furthermore, it is unlikely that significant simultaneous exposure to PB and insecticides/repellents occurred. PB was most likely used during Operation Desert Storm lasting from late January to late February 1991. Insecticides and repellents, however, were most likely used during the summer months when insects are a particular problem. During the winter insects generally are not a problem that would lead to significant personal application of insecticides and repellents.

With respect to PB alone, the IOM panel concluded that PB is a well-studied medication belonging to a class of drugs about which extensive knowledge exists and that PB could interact with other compounds to cause acute and short-term problems, but was unlikely to cause chronic effects.

The determination that chemical agents (sarin in particular) were present in a munitions depot destroyed by US troops in Khamisiya, Iraq, on March 4 and March 10, 1991 has raised the possibility of exposure to chemical agents of these troops. Allied bombing of chemical weapons storage sites in Muhammadiyat and Al Muthanna has also raised concerns. Thus far, model calculations (CIA, 1996) of plumes from these events predict potential troop exposures at levels that would not likely have caused any acute effects. However, model calculations of the March 10 detonation are not complete. Further assessments of risk at Khamisiyah await these results. Regardless of the outcomes of the exposure models, there is the underlying question of whether exposure to anticholinesterases, such as organophosphate pesticides and chemical agents, at low, sub-clinical levels can produce chronic effects.

The Armed Forces Epidemiology Board (AFEB) has provided a report to DoD (AFEB, 1996) on their assessment of the potential long-term effects resulting from sub-clinical exposures to chemical agents. The report concludes that the scientific literature provides no scientific evidence that acute sub-clinical exposures to either sarin or mustard can result in long-term health consequences. However, the report cites one study (Burchfield et al, 1976) which has shown in primates long-term alterations in electroencephalogram (EEG) following low-level sarin exposure. It was unclear in the paper, however, whether these low-level exposures resulted in any acute effects. Because of this the AFEB report recommends that further research (using primate models) on the long-term EEG effects of sub-clinical and clinical doses of sarin. The AFEB acknowledges in its report that the meaning of these EEG changes is uncertain.

In 1994, about 600 people in Matsumoto, Japan were poisoned with sarin by terrorists. Morita et al (1995) followed 264 people who had sought treatment. Despite frank, acute, and objectively measurable effects consistent with an acute sarin exposure, virtually all of these individuals recovered within three months with no apparent sequelae.

Despite such reassurances, there is still some uncertainty regarding long-term effects from very low, sub-clinical exposures to cholinesterase inhibitors. If there are persistent effects, it is likely they would be manifested in neuropsychological and neurological deficits.

RESEARCH QUESTION 16

Is there a greater prevalence of organic neuropsychological and neurological deficits in Persian Gulf veterans compared to appropriate control populations?

Early studies of neuropsychological and neurological outcome suggest that self-selected Persian Gulf veterans demonstrate subtle differences from controls. Goldstein et al (1996) found that Persian Gulf Registry participants may have small, clinically insignificant neuropsychological deficits which could be related to the presence of psychological comorbidity. A study by Jamal et al (1996) found that Persian Gulf veterans who self-report with symptoms shows evidence of small alterations in peripheral nervous system function. However, these findings are probably confounded by several biases, including that of selection.

A study has been conducted of the acute interactions of PB, DEET, and permethrin when administered orally to rats (US Army, 1995). The endpoint studied was lethality at very high doses. They found potential synergism of effect when PB was combined with DEET and permethrin. More recently, a study by Abou-Dohia et al (1996) indicates that at high, non-lethal doses, there are acute synergistic neurotoxic effects in a chicken model. The relevance of high dose acute toxicity studies to the potential for chronic effects from acute low-level exposures is unknown.

A pilot clinical program at the Birmingham, Alabama, VA Medical Center has conducted neuropsychological tests on veterans from the VA Persian Gulf Registry who self-report exposure to environmental hazards including chemical weapons. Preliminary evidence (Kotler-Cope et al, 1996) does not show any pattern to indicate a common, identifiable neuropathologic process.

Research Underway

PROJECTS VA-2, 4A, 5A, 6-Core; DoD-1A, 1E, 32, 40; HHS-1: Prevalence of symptoms associated with neuropsychological and neurological deficits will be estimated, compared to an appropriate control population, and assessed in relation to significant subgroups of the veteran population, including those self-reporting specific exposures. DoD-40 does not investigate prevalence but is a longitudinal study to examine the time course of neuropsychological function in veterans with PTSD.

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PROJECTS VA-4A, 4B, 5, 6A, 9, 10, 11: Components of these projects administer specific neuropsychological and neurological tests to groups of Persian Gulf veterans and Persian Gulf era veterans.

PROJECT VA-4A, 4B: In addition to research focusing on Persian Gulf veterans, investigators at the Boston VAMC Environmental Hazards Research Center are collaborating with scientists at St. Luke's Hospital in Tokyo, Japan. They are studying the long-term consequences of sarin exposure in individuals hospitalized following the terrorist incident in the Tokyo subway in June 1995. This should provide additional insight into long-term consequences from low-level exposures. The Boston VAMC researchers are also collaborating with scientists in Denmark who are studying Danish Persian Gulf veterans.

PROJECTS DoD-7A: This project will utilize a rat model to investigate the potential effects of depleted uranium on the nervous system.

Additional Research Needed

- Epidemiological investigations (if feasible) of the health of Persian Gulf veterans present at the detonation of the weapons depot at Khamsiyah in March 1991;
- Epidemiological investigations (if feasible) of the long-term effects of acute exposure to low-levels of chemical warfare agents;
- Toxicological investigations of the potential for long-term effects resulting from low-level exposures to chemical agent insufficient to induce acute effects;
- Development of a long-term strategic plan for research into the potential long-term health consequences of exposure to low-levels of chemical agents.

RESEARCH QUESTION 17

Can short-term, low-level exposures to pyridostigmine bromide, the insect repellent DEET, and the insecticide permethrin, alone or in combination, cause short-term and/or long-term neurological effects?

Statements that PB alone is safe and well tolerated are supported by a recent DoD-sponsored study (US Army, 1996) that investigated the side-effects of pyridostigmine bromide administered to healthy male and female volunteers in a double-blind protocol. PB (30 mg every 8 hours) or placebo was administered for 21 days (plus one dose). Anticipated side effects in the PB groups were observed although they occurred in only a few subjects and were generally mild. Four out of 60 subjects receiving PB experienced diarrhea and abdominal pain. The gastrointestinal side effects are consistent with the muscarinic effects of PB. There were no differences in side effects between males and females. Vital signs, laboratory tests, and ECG were not different between PB and placebo groups. A one year follow-up showed no adverse long-term effects. A single subject was diagnosed shortly after the dosing phase with a Fixed Drug Eruption that resolved with topical steroid treatment. The IOM panel recommended that

the possibility of chronic neurotoxic effects from short-term low dose administrations needs to be tested in appropriate animal models (IOM, 1995; see Section 4.2, Health Outcomes).

Research Underway

PROJECT DoD-2: In addition to examining physiological and neurobehavioral effects of simulated pollutant exposures, laboratory animals will be tested with pollutants alone and in combination with PB.

PROJECTS DoD-21, 33: These projects investigate blood cholinesterase and the possible role variability in cholinesterase levels might play in predisposing some individuals to adverse reactions to otherwise low doses of anticholinesterases.

PROJECT DoD-37: This project is investigating the possible neurobehavioral and immunological responses of male and female rats to various combinations of PB, DEET, and permethrin.

PROJECT VA-5D: This project is investigating the interactive effects of pyridostigmine bromide and stress in a stress-sensitive animal model.

PROJECT VA-6C: This project is investigating in-vitro the combined neural effects of hydrocarbon solvents and pyridostigmine bromide.

PROJECTS VA-4A, 4B, 5A, 6A: Components of these projects are examining a variety of neurological and neuropsychological endpoints on selected cohorts of Persian Gulf veterans and Persian Gulf era veterans. Endpoints being examined range from nerve conduction velocity studies, to olfactory evoked potentials, to performance on computerized neurobehavioral test batteries. Results will be related to potential self-reported exposures to neurotoxic compounds.

Additional Research Needed

- The ongoing clinical and toxicological studies will determine the need for additional studies.

4.2.7 Psychological/Psychiatric Outcomes

A variety of symptoms have been reported by Persian Gulf veterans. Some symptoms may be related to post-traumatic stress disorder (PTSD). Published findings (Sutker et al, 1993; Sutker et al, 1994a,b; and Wolfe et al, 1993) suggest an increased prevalence of PTSD and other psychiatric diagnoses, such as depression, in some Persian Gulf veterans. Ursano and Norwood (1996) provide a comprehensive review of this issue. Although the prevalence of psychiatric disorders has been found to be lower in Persian Gulf veterans than among Vietnam veterans, it is evident that stressors during the Persian Gulf conflict were sufficient to cause significant psychiatric morbidity. Because of the low-level of combat experienced by many troops in the Persian Gulf conflict, the presence of psychiatric problems among some returnees suggests the

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importance of stress other than actual combat as a precipitating factor. All three review panels (DSB, NIH, and IOM) recognized unusual stressors (e.g., sudden deployment, crowded living conditions, threat of CBW, combat) associated with the deployment and the possibility of their effects on mental health. Additionally, the potential effect of psychological stress on the immune system needs to be considered.

RESEARCH QUESTION 18

Do Persian Gulf veterans have a significantly higher prevalence of psychological symptoms and/or diagnoses than do members of an appropriate control group?

In a study of 1498 Seabees (Kaiser et al, 1995), service members who had been deployed to the Persian Gulf had higher scores on abnormal psychological variables.

Research Underway

PROJECTS VA-2, 4A, 5A, 6-Core, 7, 8, 12; DoD-1A, 1E, 6B, 30, 39, 40; HHS-1, 2: Components of these projects are collecting survey questionnaire data from which extensive questioning will allow development of prevalence estimates of psychological symptoms and diagnoses in comparison to an appropriate control. DoD 30 and DoD-39 will be focusing on women veterans and British veterans respectively. DoD-40 does not determine symptom or illness prevalence but is a longitudinal study of PTSD. Investigators with the Boston VAMC Environmental Hazards Research Center have established collaborations with Japanese scientists to look at psychological/psychiatric outcomes in persons exposed to sarin in the Tokyo subway terrorist incident of June 1995. These investigators are also collaborating with Danish scientists who are studying Danish Persian Gulf veterans.

PROJECTS VA-4A, 5C, 6B: Components of these projects are examining the relationship between symptoms/symptom complexes (such as chronic fatigue syndrome) and the presence of any psychological symptoms and/or diagnoses.

PROJECT VA-4A, 5B, 5C: Components of these projects investigate the immunological status among different symptomatic groups of Persian Gulf veterans. Relationships between psychological stress and altered immune function are being explored.

Additional Research Needed

- The ongoing epidemiological and clinical studies will determine what, if any, additional studies are required.

4.2.8 Infection***Leishmaniasis***

Unlike veterans with less well-defined illnesses, all but one of 12 veterans diagnosed with viscerotropic leishmaniasis had objective signs of disease, including high fever, lymphadenopathy and hepatosplenomegally. Nevertheless, because of the possibility of subclinical infection and the late presentation of this disease due to the prolonged incubation period, all three review bodies recommended further studies on detection and treatment of leishmaniasis. The IOM Committee recommended that when a serological test or other easy-to-use screening test(s) becomes available, an epidemiological and seroepidemiological study of leishmaniasis in Persian Gulf veterans should be conducted with appropriate controls. Although it appears now that infection with *L. tropica* is probably not a major risk factor for Persian Gulf veterans' illnesses, maintaining the current research effort is of value for potential concerns related to future deployments, and for taking advantage of research opportunities that could arise in the future.

Other Infections

Other infectious agents, such as mycoplasmas, bacteria, viruses, and fungi, are unlikely. Nevertheless, in spite of the absence of a strong case from clinical evaluations to support infectious agents as possible etiologic factors, targets of opportunity for collecting serological data should be exploited.

RESEARCH QUESTION 19

What is the prevalence of leishmaniasis and other infectious diseases in the Persian Gulf veteran population?

Research Underway

PROJECT VA-5A: As a component of this project, blood mononuclear cells from Persian Gulf veterans (from existing study populations) will be tested for reactivation for Epstein-Barr Virus, Cytomegalovirus, herpes-6, and herpes-7. Comparisons with appropriate control populations will be made.

PROJECT VA-15,16: These projects are directed at treatment and prevention of leishmaniasis.

PROJECT DoD-8A, 38: In DoD-8A a recombinant antigen has been characterized that detects immune response in patients with viscerotropic leishmaniasis. DoD-38 is also focusing on the development of skin and serologic assays for leishmaniasis.

PROJECT DoD-9: This project is attempting to identify the gene in humans that controls for tropism of *L. tropica* with the hope of determining which Persian Gulf

veterans, with latent *L. tropica* infection, are at risk for developing disease in the event of future immune suppression.

PROJECT DoD-12: This project involves the development of a forward-deployable infectious disease diagnostic laboratory.

PROJECT DoD-13: This project is examining dogs that were in the Persian Gulf theater to determine if they have any infections of importance to humans.

PROJECTS DoD-42, 47: These projects are investigating whether mycoplasma infection can be detected in individuals from a sample of Persian Gulf War veterans in comparison to a control group.

Additional Research Needed

- Because adequate serologic testing is not currently possible, the true prevalence of *L. Tropica* infection cannot be estimated. If such a test becomes available, seroepidemiologic studies may be undertaken. If feasible and practical, sera should be stored in expectation of such studies.

4.2.9 Cancer/Neoplastic Disease

The occurrence of some cancers among Persian Gulf veterans, although infrequent, has elevated concern over the possibility that these cancers may be linked to service in the Persian Gulf. The DSB, in examining the VA Persian Gulf Registry data, found no discernible demographic, military, or pathological pattern to the distribution of cancer cases (DSB, 1994). However, the DSB pointed out that any conclusions based on the Persian Gulf Registry must be made with caution because it is a self-selected group of veterans. The DSB also pointed out that because of the long latency period associated with cancer originating from environmental causes, it is too early to evaluate cancer risk in Persian Gulf veterans.

RESEARCH QUESTION 20

Do Persian Gulf veterans have a greater risk of developing cancers of any type when compared with an appropriate control population?

The mortality experience of Persian Gulf veterans compared with non-deployed era veterans has been investigated (Kang and Bullman, 1996). No disease-specific increase in mortality was observed in the deployed compared with the non-deployed veterans. Specifically, there was no difference in prevalence of death from neoplastic disease between Persian Gulf veterans and Persian Gulf era veterans. It has also been determined that there is no difference in hospitalization rates for neoplastic disease for Persian Gulf veterans compared with era veterans (Coate et al, 1995).

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PROJECT VA-4C: A component of this project involves establishing the basis for a cancer surveillance system among Persian Gulf veterans in the state of Massachusetts.

PROJECT DoD-1F: This project is reviewing hospitalization records for both active duty and non-active duty veterans in California.

PROJECT DoD-7B: This project uses a rat animal model to investigate the carcinogenic potential of embedded depleted uranium fragments.

Additional Research Needed

- A system for examining cause-specific, long-term mortality among Persian Gulf veterans (see below) will be useful in providing information on future cancer mortality rates among Persian Gulf veterans.

4.2.10 Mortality Outcomes**RESEARCH QUESTION 21**

Are Persian Gulf veterans experiencing a mortality rate that is greater than that of an appropriate control population? Are specific causes of death related to service in the Persian Gulf?

The cause-specific mortality experience of 695,292 service members deployed to the Persian Gulf during Operations Desert Shield/Desert Storm between August 1990 and April 1991 was compared to 746,038 non-deployed US service members (Kang and Bullman, 1996). Follow-up of these veterans covered the period beginning May 1, 1991, or the date they left the Persian Gulf area alive, and September 31, 1993. During the defined period there were a total of 1,765 deaths from all causes among deployed veterans while the number expected in a comparable US civilian population was 4,011. The observed deaths *due to all causes* among deployed Persian Gulf veterans was, however, greater than that in a comparable non-deployed military population during the same time period. These excess deaths among deployed veterans are primarily attributed to external causes, including all types of accidents and motor vehicle accidents. No excess deaths were observed for suicide and homicide among the Gulf veterans. Postservice increases in mortality due to external causes have been previously documented (Boyle et al, 1987). When deaths due to accidents, suicide, and homicide (external causes) were excluded (leaving only disease-related causes of death), the number of deaths among deployed veterans was 337 while the number expected was 382 based on the mortality rate among the non-deployed veterans. The computed disease-related death rates using these data are not different between deployed and non-deployed veterans. Despite the difference in overall mortality between deployed and non-deployed, DoD completed a study (Writer et al, 1995) comparing the one year, in-service mortality experience of service members who served in Operations Desert

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Shield/Desert Storm to that of service members who served during the same time period but were not deployed to Southwest Asia. No difference in mortality over that period was found. The latter two investigations have only examined mortality rates over short time frames and, thus, cannot be used to draw any definite conclusions about Persian Gulf veterans' mortality over longer periods of observation time.

Research Underway

None

Additional Research Needed

- Mortality experience follow-up at appropriate future time-points.
- Investigation of the specific cause(s) of excess deaths by external causes in veterans deployed to war zones. Such an investigation should not be limited to the Persian Gulf War.

5. SUMMARY AND RECOMMENDATIONS

Since the end of the Persian Gulf conflict and the first reports of health problems in Persian Gulf veterans, the federal government has acted to ensure that veterans have access to medical care, can pursue appropriate avenues for compensation, and are informed of the various programs and activities made available to them by the VA and DoD. Research is now moving forward to address important questions, the answers to which will help guide health care professionals in their treatment of Persian Gulf veterans and will enhance our ability to minimize reoccurrence of such phenomena in future deployments. The *Working Plan* was developed in 1995 to bring coherence to the research efforts being conducted or sponsored by the federal government, and to assist federal decision makers in the pursuit of various research directions.

In the introduction, three goals were articulated for research on Persian Gulf veterans' illnesses:

1. Establish symptom and illness prevalence;
2. Identify risk factors; and
3. Identify diagnostic, treatment, and prevention methodologies.

The federal government is currently invested in all three goals and has made progress toward achievement of them. There are early indications that Persian Gulf veterans are reporting an excess of symptomatic complaints, but that these are somewhat diffuse in nature and not accompanied by any definite physical pathology. Results of mortality and hospitalization studies indicate that Persian Gulf veterans are not suffering from an excess of life-threatening diseases. It is evident, though, that the greatest need for research at the present continues to be in the area of epidemiology to ascertain symptom/illness/disease prevalence. Without definitive information in this regard it cannot be quantitatively determined whether Persian Gulf veterans are actually experiencing unusual or unexpected health problems; and if they are, the extent of the problem. The VA Persian Gulf Registry and the DoD Comprehensive Clinical Evaluation Program are valuable for revealing the nature of veterans symptoms and illnesses. However, they cannot, by their self-selected nature, reveal the true population prevalence of the reported symptoms and illnesses. Population-based studies are needed to obtain this information.

VA, DoD, and HHS are actively engaged in several population-based studies to determine symptom and illness prevalence. In addition, there are some small, highly focused, epidemiological efforts that are concentrating on ascertaining the prevalence of discernible symptom complexes such as chronic fatigue syndrome. Clinical investigations, as well as these ongoing epidemiological studies, are clearly important. In addition, concerns that arose more than a year ago about adverse reproductive outcomes and sexual dysfunction among veterans and their spouses added a new dimension to the problem. Although all of the major population-based studies have components associated with reproduction and sexual function, the 1995 *Working Plan* identified a need for studies focused on these particular problems. New projects (DoD-35 and to a certain extent DoD-30) will be addressing reproductive concerns.

As a vital adjunct to population-based studies, quantitative exposure information is needed. If there are findings of excess symptoms and illnesses in Persian Gulf veterans, geographical and temporal exposure data that can be assigned to veterans during their Persian Gulf deployment would greatly improve the prospects for determining an association between exposure and disease. Accurate exposure data has been difficult to obtain, and this will most likely continue to be a problem.

Research aimed at the second and third goals theoretically should wait until findings from population studies are complete. A few population-based studies have begun to yield results while others are scheduled for completion in the next 12 to 24 months. Although research studies aimed at these goals are not currently as important as the population studies, they have not waited for epidemiology findings. Appropriately targeted, parallel studies investigating specific etiologic factors anticipate epidemiology findings. Furthermore, the research questions that need to be posed addressing etiologic factors should have generalizability beyond the current concerns of Persian Gulf veterans, and thus, address the needs of the third goal, i.e. the identification of diagnostic, treatment, and disease prevention methodologies. This is particularly important because some risk factors originally thought to be important have declined in likelihood as new information has become available.

The important contribution of non-federally funded research addressing common questions is recognized. Research by independent investigators, published in peer-reviewed scientific journals will continue to be evaluated and used in assessing the health consequences of service in the Persian Gulf, as well as adjusting the course of future research.

At the conclusion of the 1995 *Working Plan* several important specific areas of inquiry for which significant gaps in knowledge existed were listed. These areas of additional inquiry were cited in a Broad Agency Announcement (BAA) issued by DoD in 1995 in response to a Congressional mandate to conduct additional research by federal and non-federal investigators. The BAA sought proposals that were broadly directed toward epidemiology, clinical research, and research on pyridostigmine bromide. In June 1996 the Persian Gulf Veterans Coordinating Board announced the award of 12 new research grants as an outcome of the original BAA. These 12 were selected on the basis of scientific merit by an independent scientific review panel, and on programmatic relevance derived from the specific areas of inquiry identified in the 1995 *Working Plan*.

As a result of the evolution of our understanding of Persian Gulf veterans' illnesses, and of events and concerns not known at the time of the 1995 *Working Plan* (particularly the events at Khamsiyah and the bombings of Muhammadiyat and Al Muthanna), the Research Working Group has identified the following research issues that need further exploration in the near future:

- Follow-up of the mortality experience of Persian Gulf veterans, encompassing cause-specific mortality, at appropriate future time-points;
- More longitudinal follow-up studies of the health of Persian Gulf veterans, including those with illnesses that are difficult to diagnose;
- Critical peer-review of models used to predict exposure concentrations of environmental pollution (such as the Kuwait oil well fires) and chemical warfare

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agents (such as the demolition of weapons storage sites at Khamisiyah in March, 1991 and aerial bombing of chemical weapons facilities during the air war);

- Assessment of the potential for clinical investigations of the health status of the service members in the vicinity of Khamisiyah when weapons bunker 73 and the storage pit were detonated in March, 1991. If deemed possible, such clinical investigations should be carried out.

Additional research on health-related issues arising from the Persian Gulf experience but with potential for more general applicability to future conflicts is also recommended, including:

- Investigation of the risk factors for the development of stress-related disorders, including, but not limited to, post-traumatic stress disorder (PTSD);
- Investigation of the risk factors responsible for the observed excess mortality due to external causes (e.g., motor vehicle accidents) in veterans of all wars and conflicts;
- Exploration of the development of practical, sensitive, and specific biomarkers of exposure to chemical agents, including organophosphate nerve agents and vesicants such as sulfur mustard.
- Toxicological and, where feasible, epidemiological research on the potential for long-term health effects resulting from low-level, sub-clinical exposures to chemical agents, particularly organophosphate agents such as sarin;
- Development of a strategic plan for research into the potential long-term health consequences of exposure to low-levels of chemical warfare agents;
- If a simple, sensitive and specific, as well as economical, test for *L. tropica* infection becomes available, seroepidemiologic studies may be undertaken in Persian Gulf veterans. Indeed, when feasible and practical, sera of veterans should be stored in expectation of the possibility for such studies. Despite the declining importance of *L. tropica* as a risk factor in Persian Gulf veterans, continued research on tests for *L. tropica* infection are valuable for potential future deployments.

It is anticipated that results from ongoing studies will become increasingly available during the coming year. Because of the limited and focused nature of these studies, it is essential that a contextual framework for evaluating these results be provided in order to maximize the value of results. Therefore, it is further recommended that researchers engaged in research on Persian Gulf veterans' illnesses be brought together in the coming year for the purpose of comparing results and developing strategies for further meaningful comparisons of results.

Just as this revision of the *Working Plan* was made necessary by advances in our understanding and new factual information in the past year, it is anticipated that the *Working Plan* will require periodic revision and updates in the future.

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APPENDIX

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VETERANS' ILLNESSES RESEARCH DATABASE
FOR THE
DEPARTMENT OF DEFENSE,
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
& DEPARTMENT OF VETERANS AFFAIRS**

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Title Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors; Study 1: A Study of Symptoms Among 1500 Seabees

Research Focus: Symptoms/General Health

Research Type: Clinical Epidemiology Research

Agency DoD

Study Location Naval Health Research Center

Study Start Date 6/1/94

Estimated Completion Date 10/1/96

Project Status Ongoing

DoD-1A

Summary

OVERALL PROJECT OBJECTIVE: To identify risk factors associated with reported symptoms in an effort to determine causes for possible Gulf War-related morbidity.

SPECIFIC AIMS: Are there differences in postwar morbidity between Gulf War veterans (GWW) and nondeployed veterans (NDV)?

METHODOLOGY: Seabees who were on Active-duty and had been so since September 1990 were eligible to participate. Seabees (Navy construction workers) were interviewed at two major Seabee bases, in Port Hueneme, CA, and Gulfport, MS. After signing a consent form, volunteers completed a questionnaire, provided blood and urine specimens, and had their height, weight, and hand-grip strength measured. A systematically selected subsample also performed a spirometry test. Whole blood, sera, and urine specimens were stored at -70°C. Sera were studied for evidence of infection while whole blood specimens may be characterized for genetic markers that may explain symptoms. Also, sera collected during this study will be compared to prewar sera, which are known to be available for a majority of the study population. Urine specimens may be used to rule out chronic diseases, such as adrenal insufficiency. Hand grip strength and spirometry results were compared among symptomatic and nonsymptomatic Seabees. The questionnaire responses will be used to compare the morbidity of GWW and NDV. Internal comparisons will be made among GWW using logistic regression modeling to determine if any specific exposures are associated with any symptoms or symptom complexes.

EXPECTED PRODUCTS (MILESTONES): A comparison of morbidity between GWW and NDV Seabees will be done. Survey screening tools will be developed for posttraumatic stress disorder, chronic fatigue syndrome, and three diagnostic symptom patterns. Assays will be performed on pre- and postwar sera as infectious or other agents are identified as plausible causes of morbidity among GWW. We have gained approval to do some limited testing of blood specimens, although the exact agents and schedule of testing has yet to be determined. Additionally, we are working on two spin-off studies looking at handgrip strength and lung function. Manuscripts are being prepared for publication.

STATUS/RESULTS TO DATE: Seabees (n=1498) were surveyed and studied. Deployed Seabees self-reported a higher prevalence of exposures and symptoms, as well as higher scores for abnormal psychological variables. Data analysis is nearing completion. Screening tools for disease outcomes have been developed and associations to various exposures have been measured. We have conducted more in-depth analyses into the symptom and exposure data using cluster analysis. We have developed additional studies focusing on handgrip strength and lung function and have prepared the results for presentation. We have also started drafting manuscripts for publication.

PUBLICATIONS Kaiser KS, Hawskworth AW, Gray GC, et al. A comparison of self-reported symptoms among active duty seabees: gulf war veterans versus era controls. 123rd Annual Meeting and Exhibition of the American Public Health Association, Session 2198, 1995.

Title Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors; Study 2: A comparative study of hospitalizations among Active-duty personnel who participated in the Gulf War and similar personnel who did not.

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency DoD

Study Location Naval Health Research Center

Study Start Date 7/1/94

Estimated Completion Date 10/1/96

Project Status Complete

DoD-1B

Summary

OVERALL PROJECT OBJECTIVE: Screen Department of Defense (DoD) hospitalizations for association with Gulf War deployment; identify specific diseases or disease groups that merit further study.

SPECIFIC AIMS: Are hospitalization rates from 1991-1993 the same for Gulf War veterans (GWV) and nondeployed veterans (NDV)?

METHODOLOGY: This is a tri-service, retrospective cohort study using hospital discharge records from all DoD facilities. The study population consists of 2 groups: nearly all active-duty personnel who deployed to the Persian Gulf any time between 1 August 1990 and 31 July 1991 (N = 578,492), and a comparison group consisting of a 50% random sample of personnel who were on Active-duty as of 30 September 1990 and did not deploy to the Persian Gulf before 31 July 1991 (N = 699,792). Hospitalization records for the subjects were supplied by the DoD Manpower Data Center from all military hospitals. Each hospitalization lists up to a maximum of 8 unique discharge diagnoses. Each discharge diagnosis was classified into 1 of the 14 major classifications of disease and injuries as defined by ICD-9-CM. Multivariate logistic regression was used to compute odds ratios for hospitalization of GWV relative to EV for all 14 categories. A Cox proportional hazards model is being used to compare risks of hospitalizations among a subset of these categories.

EXPECTED PRODUCTS (MILESTONES): Hospitalization risks for gulf war veterans. Results from this study were presented at the October 31, 1995 meeting of the American Public Health Association in San Diego, CA. The manuscript for this study has been submitted to the New England Journal of Medicine, and they have requested revisions to the manuscript.

STATUS/RESULTS TO DATE: A manuscripts is being prepared. In general, the deployed group was not at an increased risk of hospitalizations after the war as compared to non-deployed personnel. However, deployed personnel were at greater risk of hospitalization for mental illnesses. Supplementary analysis of specific diagnostic categories will follow. Completed data collection. Manuscript has been submitted for publication in the New England Journal of Medicine.

PUBLICATIONS Coate BD, Anderson CM, Gray GC, Hyams KC, et al. Comparative study of hospitalization among gulf war veterans and era controls. 123rd Annual Meeting and Exhibition of the American Public Health Association, Session 2198, 1995.

Title Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors; Study 3: A comparative study of pregnancy outcomes among gulf war veterans and other active-duty personnel.

Research Focus: Reproductive Health

Research Type: Epidemiology Research

Agency DoD

Study Location Naval Health Research Center

Study Start Date 9/1/94

Estimated Completion Date 6/1/96

Project Status Complete

DoD-1C

Summary

OVERALL PROJECT OBJECTIVE: To evaluate the risk of birth defects and other adverse pregnancy outcomes diagnosed in military medical treatment facilities (MTFs). Risk and relative risk of inpatient events will be assessed based on existing data.

SPECIFIC AIMS: Within the design parameters, are Persian Gulf War veterans (GWW) at higher risk of adverse pregnancy outcomes than nondeployed veterans (NDV)?

METHODOLOGY: This is a historical cohort study of reproductive outcomes among military personnel deployed to the Gulf War compared to military personnel who were not deployed. Demographic and hospitalization data are available for approximately 500,000 GWW and 700,000 NDV from the Department of Defense Manpower Data Center. Substantial demographic information is available on all subjects, including race/ethnicity, proxy measures of socio-economic status (rank and education), and military occupation. Data on inpatient services received at military are also available and diagnoses are recorded using ICD-9-CM codes. Risk and relative risks of major birth defects will be evaluated. Potentially confounding factors such as maternal age will be evaluated. Multivariate analysis will be conducted to estimate relative risks, controlling for identified confounders. Events among female service members will be considered separately from those among spouses of male service members.

EXPECTED PRODUCTS (MILESTONES): Risk and relative risks of major birth defects will be evaluated. Results from this study were presented at the October 31, 1995 meeting of the American Public Health Association in San Diego, CA. Manuscripts will follow.

STATUS/RESULTS TO DATE: Children born to the deployed group are being compared with children born to the non-deployed group (about 40,000 total births) for major birth defects noted during delivery. Completed data collection. Manuscripts currently being prepared.

PUBLICATIONS Cowan DN, DeFraités RF, Wishik SM, Gray GC, Kuhn J, et al. Preliminary analysis of birth defects and Persian Gulf air service. 123rd Annual Meeting and Exhibition of the American Public Health Association, Session 2198, 1995.

Title Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors; Study 4: Infertility and Miscarriage in Gulf War Veterans

Research Focus: Reproductive Health

Research Type: Epidemiology Research

Agency DoD

Study Location Naval Health Research Center

Study Start Date 11/1/94

Estimated Completion Date 9/1/97

Project Status Ongoing

DoD-1D

Summary

OVERALL PROJECT OBJECTIVE: To examine if there are differences between Gulf War Veterans (GWW) and nondeployed veterans (NDV) in rates of infertility and miscarriage.

SPECIFIC AIMS: Do GWW have higher rates of infertility, delayed conception, and early pregnancy loss compared to NDV?

METHODOLOGY: This study will be accomplished over two phases. The first phase will be a questionnaire given to 8,000 couples (where either the male, female or both partners were on active duty but did not participate in the Gulf War during the period of the war). The questionnaire will be sent to either male or female service members who were either married in 1991 or are currently married. The second phase will consist of a 20 minute telephone interview of approximately 5,000 couples and era comparisons to obtain further military exposure information, medical history, and other known risk factors for infertility and early pregnancy loss (eg. diet, smoking, and alcohol).

EXPECTED PRODUCTS (MILESTONES): Complete Phase I survey by December 1996.

STATUS/RESULTS TO DATE: Phase I instrument has been mailed to the selected individuals (n = 17,133) on 28 March 1996. Approximately 4,700 surveys have been received; another 1,800 have been returned undelivered, and 506 have been returned blank (non participating). Data entry, as well as acquisition of most recent addresses for undelivered surveys is under process. Phase I instrument has been remailed to 6,700 veterans on 5 July 1996.

PUBLICATIONS Calderon RL, Wishik SM, Gray GC, Hiliopoulos K. The Persian Gulf war - effects on human reproduction. 123rd Annual Meeting and Exhibition of the American Public Health Association, Session 2198, 1995.

Title Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors; Study 5: Seabee Health Study.

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency DoD

Study Location Naval Health Research Center

Study Start Date 1/1/96

Estimated Completion Date 10/1/11

Project Status Ongoing

DoD-1E

Summary

OVERALL PROJECT OBJECTIVE: To study the health of Navy Seabees in relation to their deployments and the possible latent effects of Gulf War service.

SPECIFIC AIMS: 1. To determine if gulf war veterans have greater frequency of symptoms, illness, and propensity for making cognitive errors than other veterans. 2. To assemble a cohort for research on long-term effects of the gulf war on morbidity.

METHODOLOGY: The proposed study will be a nonconcurrent historical prospective study of all seabees who were on active duty for a least one month between August 2, 1990 and June 30, 1991. This group of approximately 17,500 current active duty, reservists, and former military personnel has been identified from records of the Defense Manpower Data Center. The study subjects will be mailed a survey to assess their current health status and their role (if any) in the Persian Gulf war. Participants in the survey will be followed prospectively for 15 years with a follow-up survey every 5 years (in 2001, 2006, and 2011) to detect possible latent effects of Gulf war on health. Potential sequelae include heart disease, diabetes, hypertension, arthritis, chronic inflammatory disease, psychiatric disease, and neurologic disease. To evaluate reliability of information, 2% of the survey participants will be interviewed by telephone and information on health and symptomatology from routine physicals will be collected from military medical records. Bivariate and multivariate analyses will be used to identify risk factors associated with the outcomes of interest and multivariate logistic regression modeling will be applied to evaluate relationships between risk factors and the health outcomes. Development of latent chronic disease will be monitored by calculating the cumulative prevalence rates after each 5 year survey follow-up and comparing the baseline prevalence.

EXPECTED PRODUCTS (MILESTONES): Baseline and first telephone survey data showing initial symptom prevalences will be available by March 1996. Subsequent analyses of symptom and morbidity data from written and telephone surveys are expected by March 2001, March 2006, and March 2012. A comprehensive report showing comparisons between Gulf war veterans and other veterans including a summary of risk factor associations with morbidity will be completed by October 2011.

STATUS/RESULTS TO DATE: Pilot test of the survey instrument has been completed. Awaiting OMB approval. After OMB approval, the survey instrument will be finalized and mailed to approximately 17,000 Seabees/former Seabees. First results should be available in December 1996.

PUBLICATIONS none to date

Title Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors; Study 6: A Comparison of Nonfederal Hospitalization Experience Among Veterans in California who have separated from active service: PGW vs. EV.

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency DoD

Study Location Naval Health Research Center

Study Start Date 6/1/95

Estimated Completion Date 6/1/97

Project Status Ongoing

DoD-1F

Summary

OVERALL PROJECT OBJECTIVE: To determine if the federal and non-federal hospitalizations rates differed among Gulf War Veterans (GWW) and nondeployed veterans (NDV).

SPECIFIC AIMS: The specific research questions this project will address include:

Did the causes for hospitalization rates of GWW and NDV differ in (1) military and (2) nonfederal facilities?

Did the proportional distribution of causes for hospitalization differ during the prewar and postwar periods?

Did morbidity patterns differ between GWW and NDV, temporally, and by type of hospital?

METHODOLOGY: The study population will consist of GWW and NDV who resided in California after the Gulf War. Military hospitalization data will be obtained from The Department of Defense Manpower Data Center (DMDC). Each hospitalization lists up to 8 unique discharge diagnoses, which are classified into 1 of the 14 major classifications of disease and injuries as defined by the ICD-9-CM. Information on nonfederal hospitalization will be obtained for California residents from two sources: (1) The Office of Statewide Health Planning and Development (OSHPD), which maintains the Patient Discharge Data Program, a database of hospital discharge information from all nonfederally licensed hospitals in California and (2) the Department of Veterans Affairs Patient Treatment File (VAPTF) of all VA hospitalizations.

Two registry matches will be performed. The DMDC database will be matched with the OSHPD and the VAPTF files to obtain nonfederal hospitalization data for GWW and NDV.

The proportional distribution of causes for hospitalization of GWW and NDV during the prewar and postwar periods, and by hospital facility (military compared to nonfederal), will be computed through univariate and multivariate analyses.

EXPECTED PRODUCTS (MILESTONES): Hospitalization rates in military and nonfederal hospitals will be compared between separated and active duty GWW and NDV during the prewar and postwar periods.

Characteristics of morbidity resulting in hospitalizations at nonfederal hospitals for GWW and NDV will be described.

STATUS/RESULTS TO DATE: A computerized matching program was designed by the California OSHPD to enable linkage of their database of nonfederal hospital discharge information to a NHRC database consisting of identifying and demographic data for GWW and NDV. Negotiations for the terms of this collaboration are near completion. Data from NHRC will be provided to OSHPD, presumably Fall 1996.

PUBLICATIONS none to date

Title Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors; Study 7: Prevalence of Congenital Anomalies Among Children of Persian Gulf War Veterans.

Research Focus: Reproductive Health

Research Type: Epidemiology Research

Agency DoD

Study Location Naval Health Research Center

Study Start Date 6/1/95

Estimated Completion Date 6/1/97

Project Status Ongoing

DoD-1G

Summary

OVERALL PROJECT OBJECTIVE: To determine if the prevalence of congenital anomalies in the children born to Gulf War Veterans (GWV) exceed those of children of (1) nondeployed veterans (NDV) and (2) the general population (excluding GWV and NDV).

SPECIFIC AIMS: The specific research questions this project will address include: (1) Did the overall prevalence of congenital anomalies differ among infants of GWV, NDV, and the general population prior to and after the Persian Gulf War? (2) Did the diagnostic-specific prevalence of congenital anomalies differ among infants of GWV, NDV, and the general population prior to and following the Persian Gulf War? (3) What were the pathologic patterns of congenital anomalies among children born to GWV? How did these characteristics differ by military subpopulations (e.g., service, occupation, geographic location)?

METHODOLOGY: The Department of Defense Manpower Data Center (DMDC) maintains a database of demographic, military and hospitalization data among military personnel. The state health departments of Arizona, Arkansas, California, Georgia, Hawaii, Iowa, and Oklahoma conduct active surveillance of congenital anomalies through the initial 12 months of life. Live births and fetal deaths occurring after 20 weeks of gestation are recorded in the Birth and Death Certificate Records of the Vital Statistics Registries of these states.

Two registry matches will be performed. The DMDC database will be matched with the Vital Statistics Registry of each of these seven states to identify live births and fetal deaths occurring among conceptions of GWV and NDV between 1989 and 1993. Names common to the DMDC and Vital Statistics Registries will be matched with the Birth Defects Registry of each state. Overall and diagnostic-specific rates of congenital anomalies will be calculated and compared among infants of GWV and NDV and the general population (excluding GWV and NDV) of each state.

Chi-square and Fisher's exact (two-tailed) tests will be applied to compare rates between subpopulations. Stepwise logistic regression will be applied to identify characteristics associated with congenital malformations. Cluster analysis will be performed to detect interrelations among selected anomalies and subpopulations.

EXPECTED PRODUCTS (MILESTONES): The overall as well as diagnostic-specific prevalence rates of congenital anomalies, among children of GWV and NDV will be determined. Pathologic patterns of congenital malformations among children of GWV will be described, and may serve useful in developing hypotheses about genetically or environmentally-induced birth defects for future investigations.

STATUS/RESULTS TO DATE: Data provided by the Hawaii Birth Defects Monitoring Program are being analyzed to compare overall or organ-specific rates of birth defects among infants of GWV, NDV, and the civilian population. Data collection from the Arizona Health Department began in April 1996.

PUBLICATIONS none to date

Title Physiological and Neurobehavioral Effects in Rodents from Exposure to Pyridostigmine, Fuels, and DEET (short title: Toxicity of Simulated PGW Exposure)

Research Focus: Pyridostigmine Bromide

Research Type: Basic Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 7/1/94

Estimated Completion Date 10/1/97

Project Status Ongoing

DoD-2

Summary

OVERALL PROJECT OBJECTIVE: This project will evaluate the potential of a simulated Persian Gulf War (PGW) exposure consisting of multiple chemical exposures, alone and in conjunction with an imposed psychological stressor, to induce biological effects in Sprague-Dawley rats. Effects will be evaluated for similarity to symptoms and effects reported by exposed PGW veterans (e.g., "Persian Gulf Veterans' Illnesses"). No animal model for PGVI currently exists; therefore, the project will investigate if the rodent model can reproduce the symptoms reported in PGVI.

SPECIFIC AIMS: The primary research hypothesis to be tested is that simultaneous exposure to a combination of chemical stressors, each well tolerated individually, causes subtle physiological changes when coupled with psychological stress. The study intends to identify, in Sprague-Dawley rats as an appropriate animal model, effects reported by humans similarly exposed during the PGW. The study also intends to identify a biomarker for use in evaluating the extent of exposure and of effect in humans. The study will investigate physiological and neurobehavioral effects, neurotransmitter levels, and changes in protein composition in serum/plasma, liver, kidney, testes, and brain from exposed rats.

METHODOLOGY: The chemical stressors and routes of exposure to be evaluated are: inhalation of fuel vapor (diesel, jet fuel) and their combustion products, dermal absorption of the insect repellent, N, N-diethyl-m-toluamide (DEET), and oral (or i.p.) administration of the anti-nerve agent enhancer, pyridostigmine bromide (PB). The psychological stress will be simulated by the intermittent administration of a mild electrical shock. The shock will be administered randomly by a computer controlled apparatus, so that to the experimental animal the shock will be uncontrollable and unpredictable; therefore functioning as a traumatic stressor. Male Sprague-Dawley rats will be exposed by inhalation to diesel and/or jet fuel vapor, orally to PB, and dermally to DEET, alone, and in various combinations. Half of the animals will receive a periodic, random, mild electrical shock as a psychological and neurobehavioral changes by standard tests, immediately after exposure and after a 60-day latent period. At sacrifice, neurotransmitter levels; protein mapping (i.e., stress protein induction) in brain, testes, kidney, liver, and serum/plasma; neurotoxic esterase and acetylcholinesterase activity; clinical chemistry, and immune function will be measured.

EXPECTED PRODUCTS (MILESTONES): This study will evaluate the potential of a simulated Persian Gulf War (PGW) exposure consisting of multiple chemical exposures, alone and exacerbated by an imposed psychological stressor, to induce toxic effects in Sprague-Dawley rats similar to those reported by Persian Gulf veterans experiencing symptoms thought by some to be related to the Persian Gulf War. Currently, no animal model for PGVI exists. This study will investigate, in a rodent model, factors that may have contributed to the development of the symptomatology reported in PGVI. Representative chemical exposures from the PGW theater, with and without an imposed psychological stressor, will be investigated individually and in combinations to determine possible interactive effects. Selected physiological and neurobehavioral tests, neurotransmitter levels, and expression of stress proteins and/or shifts in protein charge characteristics will be used to correlate findings observed in Sprague-Dawley rats with the physiological and psychological symptoms commonly reported in PGVI.

STATUS/RESULTS TO DATE: Ongoing. Animal exposure system modified to administer electric shock as psychological stressor was successfully tested. The fourteen day exposure of male Sprague-Dawley rats to inhaled JP4 jet fuel vapor, oral pyridostigmine bromide, and dermal DEET has been successfully completed. The first data set has been collected and is being analyzed. The second data set was collected in mid-September and data analysis will continue until December.

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1996.

PUBLICATIONS Nelson RA. Determining Types of Health Effects to Persian Gulf Veterans Due to Exposure to Occupational Hazards, Thesis No. AFIT/GEE/ENV/95D-13, Air University, USAF Institute of Technology, Wright-Patterson Air Force Base, OH. 1995.

Title The General Well-Being of Gulf War Era Service Personnel from the States of Pennsylvania and Hawaii: A Survey

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 9/1/92

Estimated Completion Date 5/20/94

Project Status Complete

DoD-4

Summary

OVERALL PROJECT OBJECTIVE: Assess the general sense of well-being of Gulf War era veterans in the States of Hawaii and Pennsylvania.

SPECIFIC AIMS: Identify groups within the population reporting physical or mental distress and highlight probable causes or contributing factors. Ascertain whether any group within this population was at risk for future development of PTSD related to their Gulf War era experiences. Evaluate the status of the 14th Quartermaster Detachment. Assess the impact of the casualties of the 14th Quartermaster Detachment on the community of Greensburg, Pennsylvania.

METHODOLOGY: Identified citizens of Pennsylvania and Hawaii who served during the period of Operation Desert Shield/Storm (16, 167). Solicited voluntary participation in completing questionnaires, interviews, and other study materials (approx. 14,100). Designed and administered study materials (4,334 responses). Integrated data from an additional 25,000 individuals being studied as part of a larger assessment as a sample population from which to draw inferences. Survey instruments and methods included a questionnaire, Impact of Events Scale, Brief Symptom Inventory, PTSD Risk Algorithm, records/reports from Pacific Center for PTSD and from PTSD Clinical Team, VA Medical Center, Pittsburgh, PA. A variety of statistical analyses were applied to the data, scores, and indices. The distribution of psychological symptoms in the samples was analyzed, as was the distribution of illness symptoms as another category of risk. The significance of the differences in psychological and physical symptoms between deployers and nondeployers was examined.

EXPECTED PRODUCTS (MILESTONES): An assessment of the general physical and mental well-being of the subject population. Information to assist Congressional determination of the need for appropriated funds for specialized counseling and support services to counter any adverse effects of service during Operation Desert Shield/Storm. Information addressing potential links between service in the Gulf and subsequent health and adjustment difficulties upon return.

STATUS/RESULTS TO DATE: Study completed. Results published. The studied population was generally well-adjusted, with subgroups experiencing either physical symptoms, high levels of stress, or both (about 15% of the population). Among those deployed and who reported physical symptoms, neither stress nor exposure to combat or its aftermath bear much relationship to their distress; only the fact of deployment differentiates them from their less-burdened counterparts. About 15% of those deployed were experiencing both stress and physical symptoms at the time of the study. Many of these seem at risk for development of further difficulty, particularly PTSD.

PUBLICATIONS US Army Medical Research and Materiel Command Report. The General Well-Being of Gulf War Era Service Personnel from the States of Pennsylvania and Hawaii: A Survey. May 1994.

Title Combat Stress Pharmacotherapy

Research Focus: Brain & Nervous System

Research Type: Basic Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 10/1/88

Estimated Completion Date 9/30/99

Project Status Ongoing

DoD-6A

Summary

OVERALL PROJECT OBJECTIVE: Combat stress reaction (CSR) and posttraumatic stress disorder (PTSD) are thought to be part of a common spectrum of disorders. It is essential to develop animal models for combat stress reaction, to identify neurochemical mechanisms of, and pharmaceutical countermeasures for combat stress effects. Emphasis is on rapidly acting countermeasures which could be administered far forward, and which would allow the stress casualty to remain on duty and prevent the development of PTSD. Pharmaceutical countermeasures must be free of unwanted side effects, such as sedation or impairment of memory or performance.

SPECIFIC AIMS: Evaluate clinical and pre-clinical pharmaceuticals to prevent/reverse conditioned defeat (CD). Use acoustic startle, the swim test, neuroendocrine markers and telemetric monitoring of heart rate in behaving, unrestrained animals exposed to threat, develop technology for predicting vulnerability to conditioned defeat; thus enhancing evaluation of possible preventive measures.

EXPECTED PRODUCTS (MILESTONES): FY 97: Examine the effect of valium on CD in another species (mice) to test the generality of the finding that valium may exacerbate CD (and might be contraindicate in combat stress reaction). Extend testing to include benzodiazepine antagonists and inverse agonists in mice. In addition, begin testing Buspirone, a clinically available, non-sedating, non-benzodiazepine anxiolytic drug in mouse CD model. Will also test its more potent pre-clinical analogs - Gepirone, ipsapirone, and tiaspirone. The startle response has been reported to be exaggerated in both CSR and PTSD. Accordingly, we will test the effect of CD on acoustic startle in the mouse. To identify potential aids to diagnosis of risk for CSR, we will further characterize hormonal responses to CD. FY 98: Begin testing other behaviorally active clinically-available drugs in mouse CD model: (a) beta blockers (atenolol); (b) antidepressants used in panic disorders (Prozac, tricyclics); (c) stimulants such as caffeine and amphetamine. Evaluate all listed compounds for capability to reverse CD-induced deficits in the swim test. FY 99: Begin testing novel pre-clinical, non-benzodiazepine anxiolytics in the mouse CD model, including cholecystokinin antagonists; corticotrophin releasing hormone antagonists; and Neuropeptide Y (NPY) agonists. Evaluate potential therapeutic effects of thyrotropin releasing hormone (TRH) - an endogenous peptide stimulant successfully employed to reverse learned helplessness. Target drug intervention at specific brain sites, study viable brain slices from defeated mice, including amygdala and hippocampus, to evaluate agents for selective effects on specific circuits involved in CD. Study the effects of CD on cognitive function and neurodegeneration.

STATUS/RESULTS TO DATE: By establishing a streamline model of conditioned defeat (CD), we have met the requirement of developing an animal model for testing diagnostics for component processes of combat stress reaction (CSR) and screening drugs for safe, rapid treatment. We have shown that CD markedly decreases activity in the swim test - a measure used in the pharmaceutical industry to screen antidepressants. In an effort to develop reliable predictors and clinical indicators for CSR, we have characterized the dramatic responses to CD of hormones stimulated via the anxiogenic peptide, corticotrophin releasing hormone (CRH). We have shown that acoustic startle response (ASR) in hamsters was exacerbated by administration of CRH. This is significant because exaggerated acoustic startle response has been validated as a biological marker for PTSD and reported as a symptom of CSR as well. We found that valium is clearly counterproductive as a treatment for hamsters, as it markedly exacerbated CD. Thus, the CD

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model affords us the capability of identifying drugs which might be contraindicated, as well as those which might be beneficial. By way of confirmation, an Israeli colleague is reporting that benzodiazepines fail to block the development of PTSD following trauma. We have optimized the CD model as a test bed for screening drugs by modifying it to deliver rapid, high-volume, low-cost throughout.

- PUBLICATIONS** Hebert M, Potegal M, Moore T, Evenson AR, Meyerhoff J. Diazepam exacerbates conditioned defeat in hamsters (*Mesocricetus auratus*). Pharmacology, Biochemistry and Behavior. In press. 1996.
- Potegal M, Ferris C, Hebert M, Skaredoff L, Meyerhoff J. Attack priming in female Syrian golden hamsters is mediated by a c-fos coupled process within the corticomedial amygdala. Neuroscience. In press. 1996.
- Potegal M, Hebert M, deCoster M, Meyerhoff J. Brief, high frequency stimulation of the corticomedial amygdala induces a delayed and prolonged increase of aggressiveness in male Syrian golden hamsters. Behavioral Neuroscience 110(2):1-12, 1996.

Title Combat Stress Diagnosis, PTSD Prevention

Research Focus: Brain & Nervous System

Research Type: Clinical Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 10/1/87

Estimated Completion Date 9/30/98

Project Status Ongoing

DoD-6B

Summary

OVERALL PROJECT OBJECTIVE: Develop diagnostic instruments for far-forward, early diagnosis of soldiers at risk for combat stress reaction (CSR) and posttraumatic stress disorder (PTSD) to allow early intervention to prevent chronic PTSD.

SPECIFIC AIMS: Use combined neuroendocrine and psychophysiologic techniques to develop rapid, reliable and inexpensive means of determining soldiers' level of stress, fitness for duty and risk of CSR/PTSD.

METHODOLOGY: We will measure salivary levels of cortisol, testosterone, and dehydroxyepiandrosterone sulfate (DHEAS) as stress indices. We will critically evaluate the reliability of voice frequency modulation as a stress index. In collaboration with the New Haven Veterans Administration we will conduct a prospective study on risk of stress reactions/PTSD in Special Operations Forces.

EXPECTED PRODUCTS (MILESTONES): FY 96: Correlate salivary cortisol and Soldier of the Month Board performance; measure effect of stress on salivary testosterone and DHEAS. FY 97: Determine effect of psychological stress on voice frequency modulation spectrum and correlate with performance as well as physiological and hormonal changes. FY 98: Complete prospective study of changes in acoustic startle and dexamethasone suppression tests (using salivary cortisol measurements) in soldiers subjected to stressful deployments.

STATUS/RESULTS TO DATE: Ongoing. Because the "Soldier of the Month (SOM) Board" is a uniquely robust physiological stressor, we have been using it as a test bed to develop and validate field-ready stress measures, such as a battery of non-invasive (salivary) hormonal measures. We will use these measures in stress studies in soldiers at risk for combat stress reaction and/or PTSD during military operations in the field. We have characterized the psychoendocrine and autonomic profile of operational stress, using the SOM Board as a model. Elevated plasma and salivary cortisol levels were measured in soldiers after an SOM Board experience. We have identified several plasma hormones which correlate positively with anxiety, and have demonstrated that anticipatory anxiety predicts poor performance.

PUBLICATIONS Pitman RK, Orr SP, van der Kolk BA, et al. Analgesia: a new dependent variable for the biological study of PTSD, In Post Traumatic Stress Disorder: Etiology Phenomenology and Treatment (ed by Wolf ME). American Psychiatric Press, pp 141-147, 1990.

Title Health Risk Assessment of Embedded Depleted Uranium: Behavior, Physiology, Histology, and Biokinetic Modeling

Research Focus: Depleted Uranium

Research Type: Basic Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 12/1/94

Estimated Completion Date 1/30/98

Project Status Ongoing

DoD-7A

Summary

OVERALL PROJECT OBJECTIVE: To evaluate health risks associated with tissue-embedded depleted uranium (DU) fragments by studying the behavioral, physiological, and histological consequences of implanted DU in a rodent model.

SPECIFIC AIMS: Specific evaluations in the DU implanted rodent model will include: 1. Behavioral tests of motor activity and memory. 2. Nerve conduction studies of peripheral nerve function. 3. Measurement of central nervous system excitability in brain slice preparations. 4. Biochemical assessments of renal function. 5. Histological assessment of local tissue damage and capsule formation. 6. Measurement of tissue concentrations of uranium. 7. Development of a biokinetic model describing the distribution of uranium over time.

METHODOLOGY: After defining appropriate doses to be used for analysis of DU effects, a study of 325 rats provides toxicity data. Rats are randomly assigned to 5 treatment groups: 1) low-dose DU, 2) medium-dose DU, 3) high-dose DU, 4) tantalum (Ta) controls, and 5) non-implanted sham-surgical controls. In the low-dose and medium-dose groups, Ta is substituted for a fraction of the DU pellets to keep the total number of implanted fragments constant. Rats are evaluated, euthanized and tissue samples taken at 1, 6, 12, or 18-months following fragment implantation. Groups of 15 rats were determined to be necessary to achieve statistical significance. Additional animals (20 rather than 15) are implanted for the 18-month time point with the expectation of a 20-25% natural mortality. Each rat is thoroughly evaluated for changes in behavior (functional battery, motor activity, passive avoidance test), peripheral nerve function (conduction velocity measurements), CNS excitability (hipocampal brain slice electrophysiology), renal function (plasma and urine biochemistries) and tissue histology including capsule formation. In addition, data on tissue uranium levels (measured by kinetic phosphorescence analysis) from a subgroup of rats is used to develop a biokinetic model to predict uranium distribution. All measured parameters are compared among groups through analysis of variance and significance accepted at the $P < 0.05$ level.

EXPECTED PRODUCTS (MILESTONES): Determine appropriate doses for a DU toxicity study in the rat: July 1995. Complete toxicity assessment at the one-month point: Dec 1995. Complete toxicity assessment at the six-month point: Dec 1996. Complete toxicity assessment at the 12-month point: June 1997. Complete toxicity assessment at the 18-month point: Dec 1997. Complete biokinetic modeling for distribution of DU fragments: Jan 1998.

STATUS/RESULTS TO DATE: Ongoing. The 30-day data following pellet implantation is complete. Fibrous tissue adheres to DU but not Ta pellets in situ, but capsule formation is not yet evident. Uranium levels are high and dose-dependent in kidney, bone, and urine and moderately high in muscle, brain and spleen. There is no evidence of renal toxicity or neurobehavioral neurotoxicity at this time and point. Results have not yet been published.

PUBLICATIONS none to date

Title Carcinogenicity of Depleted Uranium Fragments**Research Focus:** Depleted Uranium**Research Type:** Basic Research**Agency** DoD**Study Location** Ft. Detrick**Study Start Date** 1/26/95**Estimated Completion Date** 10/30/98**Project Status** Ongoing

DoD-7B

Summary

OVERALL PROJECT OBJECTIVE: To assess the carcinogenic risks associated with long-term exposure to DU-containing shrapnel in wounds.

SPECIFIC AIMS: 1. Determine the carcinogenicity of radioactive DU fragments in tissues relative to nonradioactive (tantalum) foreign-body fragments. 2. Correlate urine and kidney concentrations of Uranium with time after implantation of DU fragments.

METHODOLOGY: 1. Relative Carcinogenicity of Embedded DU Fragments. Test metals, in the form of wires or thin foils, will be surgically implanted into the subcutis of rats. Thorotrast will be used as a positive control radioactive material. These animals will be observed for two years for the onset, incidence, and biological characteristics of tumors developing at the site of implantation. The study will determine if radioactivity of DU foils will increase the carcinogenicity of larger foils, or make smaller foils carcinogenicity of tantalum foils of similar sizes. The incidence of subcutaneous tumors will be compared among dose groups by using a Cox proportional hazards model. 2. Renal Toxicity of Chronic Uranium Exposure. This study will determine the time course to achieve a steady-state renal DU concentration from an implanted source and to determine if toxicity is present at the steady-state concentration. A pilot study in rats will be conducted to determine if the urinary excretion of U from implanted DU foils is sufficiently high enough above background to detect. Urinalysis will be performed on 24-hour urine samples after animals have been acclimated to the metabolism cages. Analyses will include U concentration, pH, glucose, protein, and creatinine. Urinary enzymes will be measured for possible use in the renal toxicity study. If elevated U concentrations can be detected in the urine, the renal study will be conducted as a subset of the carcinogenesis study. Rats that are sacrificed will be examined for lesions, with particular attention to the urinary system. Kidneys will be examined histologically for lesions related to U toxicity. U content in the kidney and skeleton and remainder of the carcass will be determined. Laser phosphorim will be used to analyze tissue and urine samples for U.

EXPECTED PRODUCTS (MILESTONES): The carcinogenic hazard of radioactive DU fragments relative to nonradioactive fragments will be determined so that informed judgements can be made about the clinical management of veterans with DU fragments embedded in their soft tissues. Milestones of this study are: January 1996: Completion of pilot study. April 1996: Initiation of the long-term study of potential carcinogenic effects of implanted DU fragments. April 1998: Completion of the long-term carcinogenesis of DU fragments. October 1998: Final Report.

STATUS/RESULTS TO DATE: Ongoing. Dr. Gerhard Brand visited the Inhalation Toxicology Research Institute March 1995 to consult on the experimental design of studies using subcutaneous implants of metal in rodents. Dr. Brand developed the animal model system which is the basis for the planned carcinogenesis studies. Dr. Hahn visited the Armed Forces Radiobiology Research Institute to discuss and coordinate research approaches to the problems of DU toxicity with Armed Forces Radiation Research Institute (AFRRI) investigators. 1. A preliminary 60-day study protocol has been initiated to a) determine the early solubility of implanted DU compared with DUTi in rats and mice; b) determine the early histologic responses to implanted DU or DUTi and determine the changes in surface characteristics of DU or DUTi that may alter the long-term potential carcinogenic effects of implanted DU. This study will determine the feasibility of using a subcutaneous implantation model of foreign body carcinogenesis. 2. A significant change from initial proposal is the addition of DU (0.75% Ti) alloy as a companion with DU. Discussions with investigators at AFRRI indicated that differences in solubility may exist between these two compounds. 3. Mice were included in the pilot study since the foreign body carcinogenic model

being studied has used both rats and mice. Certain strains of mice develop foreign body sarcomas much more rapidly than other strains of mice or rats.

PUBLICATIONS none to date

Title Serologic Diagnosis of Viscerotropic Leishmaniasis (VTL)**Research Focus:** Leishmaniasis**Research Type:** Applied Research**Agency** DoD**Study Location** Ft. Detrick**Study Start Date** 10/1/93**Estimated Completion Date** 9/1/96**Project Status** Complete

DoD-8A

Summary

OVERALL PROJECT OBJECTIVE: To develop a reliable serologic test for viscerotropic leishmaniasis.

SPECIFIC AIMS: Goal is to identify an antibody (Ab)-based serologic assay to detect active infection with Leishmania parasites causing the clinical syndrome of VTL using a standard format such as enzyme-linked immunosorbent assay (ELISA).

METHODOLOGY: Use of ELISA-based assays to diagnose active infection with an infectious agent is a widely accepted and useful diagnostic intervention. Currently, there are no commercially available serologic assays to detect Leishmania infection. Some specialty labs use the indirect immunofluorescence technique (IFAT) format to detect antibodies to surface proteins of the promastigote (insect vector form of the parasite); however, the IFAT is not useful in VTL. Once the parasite is injected into humans by the sand-fly vector, it transforms into an amastigote (the form found in mammals). The amastigote is a genetically different morphologic form which expresses a unique repertoire of antigens. We believe these amastigote dominant antigens hold the key to serologic diagnosis of VTL. Using recombinant molecular biology techniques, proteins which are recognized by VTL sera can be made in large quantities and used as capture antigens in ELISA tests.

EXPECTED PRODUCTS (MILESTONES): Identification of reactive clones made from screening a genomic library of Leishmania DNA, cloning and sequencing the recombinant proteins and use of the recombinant proteins to screen sera from patients with VTL.

STATUS/RESULTS TO DATE: A genomic library was made from a Desert Storm isolate of Leishmania. Parasite DNA was sheared and introduced into E. coli via phage virus. Bacterial clones with eparasite DNA were transferred to nitrocellulose and then incubated with radiolabeled protein labeled VTL sera. Reactive clones were then isolated, induced, and protein was sequenced. Patients with VTL appear to recognize a 210 kd recombinant protein, called Lt-1, the carboxy third of the protein is made of repeats. Smaller recombinant proteins and synthetic peptides based on the repeats have been made. To date, none of these peptides reliably discriminates infected from noninfected samples. Further work in this area is being done by the contractor.

PUBLICATIONS Dillon DC, Day CH, Whittle JA, Magill AJ, Reed SG. The molecular and immunological characterization of Leishmania tropica antigens: serological and cellular responses by viscerotropic Leishmaniasis Patients. VIII Intern Congress of Parasitology, 1994.

Dillon DC, Day CH, Whittle JA, Magill AJ, Reed. The Molecular and immunological characterization of Leishmania tropica antigens: serological and cellular responses by Viscerotropic Leishmaniasis Patients. 43rd Annual Mtg AM SocTrop Med & Hyg., 1994.

Dillon DC, Day CH, Whittle JA, Magill AJ, Reed. Characterization of a Leishmania tropica antigen that detects immune responses in Desert Storm Viscerotropic Leishmaniasis patients. Proc. Natl Acad Sci., (92) :7981-82, August 15 1995.

Title Development of a Leishmania Skin Test Antigen (LSTA)

Research Focus: Leishmaniasis

Research Type: Applied Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 10/1/93

Estimated Completion Date 1/31/00

Project Status Ongoing

DoD-8B

Summary

OVERALL PROJECT OBJECTIVE: To develop a reliable skin test for Leishmania infection.

SPECIFIC AIMS: Goal is to identify a safe, potent and non-sensitizing LSTA; manufacture it under cGMP; and obtain an IND for its use in phase 1 and phase 2 clinical trials.

METHODOLOGY: Use of skin tests to diagnose prior infection with an infectious agent (e.g., tuberculosis) is a widely accepted useful diagnostic intervention. Currently there is no Leishmania skin test licensed for use in the USA or available under an IND. Once required phase 1 and phase 2 studies are completed in humans, studies could be performed in Gulf War veterans with confirmed and suspected leishmaniasis.

EXPECTED PRODUCTS (MILESTONES): Completion of the IND application by 4th Quarter FY96 and completion of phase 1 study by 2nd Quarter FY97. Phase 2 trials in FY97-98. Phase 3 trials in 98.

STATUS/RESULTS TO DATE: Ongoing. A lot of LSTA (microfluidized-lysate (MFL) - LSTA) was manufactured under cGMP in May 1995. Pre-clinical testing in guinea pigs and non-human primates has shown it to be safe and potent. A similar product has sensitized naive guinea pigs on repetitive testing but whether this will occur in humans is not known. SDS-PAGE analysis of product substance, final container product and following heat treatment has shown the MFL-LSTA to be stable. IND submitted to FDA on 6/2/96. FDA placed phase 1 protocol on clinical hold on 7/2/96 pending satisfactory response to questions relating to product safety. We believe we will be able to satisfactorily address the FDA concerns.

PUBLICATIONS Stitler JM, Ballou WR, Eckels KH, Magill AJ. Good Manufacturing Practices (GMP) Production of Leishmania Skin Test Antigen: 1. Protocol Requirements for Investigational New Drug (IND) Application. 43rd Annual Mtg of AM Soc Tropical Med & Hyg. 1994.

Stitler JM, Ballou WR, Eckels KH, Wellde BT, Topper MJ, Rowton ED, Magill AJ. Good Manufacturing Practices Production of Leishmania Skin test antigen: 2. Production of a Microfluidized Lysate. 44th Annual Mtg of AM Soc Tropical Med & Hygiene, 1995.

Title Identification of the Genetic Factors Which Control Tropism in Leishmania

Research Focus: Leishmaniasis

Research Type: Basic Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 7/1/94

Estimated Completion Date 7/1/98

Project Status Ongoing

DoD-9

Summary

OVERALL PROJECT OBJECTIVE: To identify the gene(s) that control tropism in Leishmania and determine its (their) sequence and function.

SPECIFIC AIMS: The goal of this DOD/VA research is to identify the gene(s) that control tropism in Leishmania. The identification of a "tropism" gene will: (a) Enable the development of specific gene probes (primers) to be used in a patient screening program to identify those at risk of reactivation of latent infections; (b) Address the fundamental question of infectious disease pathophysiology, namely why an organism infects a particular cell; (c) Optimize treatment regimens according to Leishmania species and the immune status of the host. The identification of the genetic factor(s) involved in the visceralization of Leishmania will require us to develop in vitro and in vivo models of tropism to facilitate the study of viscerotropic leishmaniasis (diagnosis, therapy, prevention) and Leishmania tropism.

METHODOLOGY: A. Develop in vitro and in vivo models of Leishmania tropism to use for the determination of the genetic factors controlling tropism: i) a promastigote temperature sensitivity model; and ii) a cutaneous and a visceral animal model of Leishmania tropism. B. Create Leishmania mutants with altered tropism in the in vitro and in vivo models of tropism: i) temperature sensitive parasites changed to resistant and visa versa; and ii) cutaneous parasites (in the animal model) changed to visceral and visa versa. C. Use recently developed molecular genetic techniques to restore the original (wild-type) phenotype to the Leishmania temperature and tropism mutants by transfection with the appropriate Leishmania cosmid DNA libraries. D. Identify the gene(s) controlling temperature sensitivity and tropism present in the cosmid(s) which restore(s) a wild-type phenotype to the Leishmania cells. E. Retest the function of these genes in both models using transfection methodology.

EXPECTED PRODUCTS (MILESTONES): 1. Develop an in vitro temperature sensitivity model that will correlate with tropism in vivo - 1995. 2. Develop animal models which can be used to select for altered tropism - 1995. 3. Obtain Leishmania mutants in vitro - 1995 - 1996. 4. Obtain Leishmania mutants in vivo - 1996 - 1997. 5. Create cosmid DNA libraries - 1996 - 1997. 6. Reconstitute the wild-type phenotype (tropism) utilizing a wild-type Leishmania DNA cosmid library - 1997-1998. 7. Molecular characterization: a) Identify the gene(s) present in the cosmid(s) which restore(s) a wild-type phenotype to the Leishmania mutants. b) Sequence the gene(s) - 1998. c) Determine homologies with genes in the database - 1998.

STATUS/RESULTS TO DATE: Ongoing. 1. Developed an in vitro promastigote temperature model and determined that temperature sensitivity in vitro correlates with Leishmania tropism in vivo. 2. Determined that there is no absolute temperature requirement for dermatotropism, but that there is a minimum temperature resistance requirement for visceralization. 3. Determined that parasite strains that have an unusual tropism in the human host (to include the viscerotropic *L. tropica* from Desert Storm) also show an unexpected temperature sensitivity in the model. 4. Developed two animal models where the tropism of the Leishmania strain is known, uniform, and reproducible (all organisms are found in one location, either visceral or cutaneous) when inoculated in the skin (sc) to mimic a sand fly bite: Cutaneous model - no visceralization; and Visceral model - no skin lesions. 5. Obtained Leishmania temperature sensitive and resistant mutants. 6. Developed and standardized in the laboratory transfection and Leishmania cosmid DNA library techniques. 7. Selected a *L. donovani* and two *L. tropica* temperature-resistant strains in vitro. 8. Chemically mutagenized a *L. mexicana* strain and selected a tropism mutant in our hamster model. 9. Made wild-type DNA cosmid libraries of all the Leishmania strains (4) that will be mutagenized and

selected for altered tropism in our hamster model.

- PUBLICATIONS** Callahan HL, Portal IF, Grogl M. Development of an in vivo Leishmania temperature sensitivity model: preliminary studies with strains with aberrant tropism in vivo. 44th Annual Meeting of Am Soc Tropical Med & Hygiene 53(2):215, 1995.
- Callahan HL, Portal IF, Bensinger SJ, Grogl M. The temperature sensitivity of Leishmania promastigotes in vitro: a model for tropism in vivo. 1996. Accepted, Exp. Parasit.
- Callahan HL, Grogl M. Development of animal models to study Leishmania tropism at the molecular level. 1995, in preparation for submission to the Am J Tropical Med.

Title Pyridostigmine Synergistic Toxicity Study

Research Focus: Pyridostigmine Bromide

Research Type: Basic Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 11/1/94

Estimated Completion Date 3/1/94

Project Status Complete

DoD-10

Summary

OVERALL PROJECT OBJECTIVE: To determine potential toxic interactions when pyridostigmine bromide, permethrin, and DEET are given concurrently to male rats by gavage. The after-action analyses uncovered concerns about the possible synergism of pyridostigmine taken by the service members (SM's) in ODS to protect them against potential nerve agent exposure and permethrin and DEET, insecticides used by SM's in ODS.

SPECIFIC AIMS: Phase I determined the acute oral lethal dose response relationship of each compound with the vehicle, propylene glycol. Phase II was a dose response study using probit units from Phase I as well as calculated dosage solutions of the three materials in combinations.

METHODOLOGY: The first phase was the development of acute oral lethal dose-response relationship of each compound with the vehicle, determine dosage levels for the second phase. Part 1 of Phase II served as a positive control for the interaction portion of the study and verified data obtained from Phase I. The Part 1 dose response study used probit units from Phase I. Part 2 of Phase II was similar to the control portion except that the vehicle contained the calculated LD16 of the other two compounds. All studies were conducted under Good Laboratory Practice (GLP; 40 CFR 160 and 792 and amendments). The Phase I study protocol used 16 groups of 10 animals each, with one group of 10 receiving only the propylene glycol vehicle. Gross necropsy was performed on all animals as soon as possible after death. Animals surviving the 14 day study period were sacrificed and examined for gross pathological lesions. The Phase II study used 15 groups of six animals each for the positive control portion and 18 groups of 10 animals each for the interaction portion. Animals were necropsied and examined for gross pathological lesions.

EXPECTED PRODUCTS (MILESTONES): Reports and publications.

STATUS/RESULTS TO DATE: Complete. Report published 31 May 1995. The principal finding is that there is significant increase on the lethal effect in rats given pyridostigmine bromide, permethrin, and DEET simultaneously by gavage when compared to expected additive lethal effect of the individual compounds.

PUBLICATIONS US Army Center for Health Promotion and Preventive Medicine Report. Acute Oral Toxicity Study of Pyridostigmine Bromide, Permethrin, and DEET in the Laboratory Rat. Toxicological Study 75-48-2665, 31 May 1995.

Title Male/Female Differential Tolerances to Pyridostigmine Bromide

Research Focus: Pyridostigmine Bromide

Research Type: Clinical Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 10/1/94

Estimated Completion Date 2/1/97

Project Status Ongoing

DoD-11

Summary

OVERALL PROJECT OBJECTIVE: To determine if males and females have different tolerances to doctrinal dose (30 mg every 8 hours) of pyridostigmine bromide.

SPECIFIC AIMS: To evaluate the tolerance of pyridostigmine bromide (30 mg every 8 hours for 21 days); to evaluate multiple dose kinetics; and to evaluate the effect of weight in males and females upon drug tolerance.

METHODOLOGY: Double-blind study.

EXPECTED PRODUCTS (MILESTONES): Final Report.

STATUS/RESULTS TO DATE: In life portion of the study and the one year follow-up have been completed. The draft report for the in life portion of the study is under review. Preliminary results from this study indicate that pyridostigmine continues to be safe. Expected side effects, primarily gastrointestinal, were observed. Other events did not appear to be related to the drug since the reporting incidence was equal in active drug and placebo groups. No difference in side effects were found related to gender, size, or weight. Draft report has been peer reviewed and the final report is due by December 1996.

PUBLICATIONS none to date

Title Forward Deployable Diagnostics for Infectious Diseases**Research Focus:** Miscellaneous**Research Type:** Applied Research**Agency** DoD**Study Location** Ft. Detrick**Study Start Date** 10/1/93**Estimated Completion Date** 9/30/01**Project Status** Ongoing**DoD-12****Summary**

OVERALL PROJECT OBJECTIVE: To develop a series of simple diagnostic assays suitable for forward deployed preventive medicine teams, Area Medical, and Forward Laboratories.

SPECIFIC AIMS: To develop rapid and simple diagnostic tests to permit the identification of the causes of infection outbreaks before they reach the epidemic state. Serological assays are being developed for typhus fever, dysenteries caused by shigella and other bacteria, and leptospirosis. Tests utilizing polymerase chain reaction (PCR) technology are being explored for diagnosing dengue fever. Fluorescent assays for malaria and other parasitic diseases are under investigation. Hand-held chromatographic immunoassays are being developed for dengue fever. Future applications include campylobacter, malaria, and arboviral and rickettsial disease agents. Dipstick technology is being developed for dengue fever as well as rickettsial disease agents responsible for scrub and endemic typhus, and spotted fever rump diseases.

METHODOLOGY: Hand-held chromatographic immunoassays; electrochemiluminescence (ECL) detection; polymerase chain reaction assays; dip-stick assays.

EXPECTED PRODUCTS (MILESTONES): Forward deployable assays using immunochemical - based assays against dengue, hanta-, and selected hemorrhagic fever viruses are expected to reach Milestone I in 4QFY97. Confirmatory polymerase chain reaction assays with high specificity and sensitivity are expected to reach Milestone I in 4QFY98. Field evaluations of selected dip-stick assays will occur during FY96.

STATUS/RESULTS TO DATE: Sensitive and specific enzyme-linked immunoassays are currently available for the detection of selected antigens, or anti-agent IgG/IgM antibodies for a select group of infectious diseases. Application of chromatographic assay technology is expected to occur in FY96 with completed products available by FY98. Prototype polymerase chain reaction assays are currently available for dengue virus and hantaviruses. New PCR technology that will allow automated detection is currently being explored. Evaluation of fieldable reagents and validation of the assays will continue at least until FY98. Initial laboratory development is completed for dip-stick assays for scrub and endemic typhus; dip-sticks for rickettsial spotted fever group and dengue fever disease agents are in progress, and should be completed in FY97; field evaluations follow laboratory development. Laboratory development is in progress for hand-held immunoassays for dengue fever viruses.

PUBLICATIONS Kelly DJ, Chan CT, Paxton H, Thompson K, Howard R, Dasch GA. Comparative evaluation of a commercial enzyme immunoassay for the detection of human antibody to Rickettsia typhi. Clinical & Diagnostic Laboratory Immunology 2(3):356-60, 1995.

Weddle JR, Chan TC, Thompson K, Paxton H, Kelly DJ, Dasch GA, Strickman D. Effectiveness of a dot-blot immunoassay of anti-Rickettsia tsutsugamushi antibodies for serologic analysis of scrub typhus. Am J Tropical Med & Hygiene, 53(1):43-6, 1995.

Title Effects of Persian Gulf War Service on Military Working Dogs**Research Focus:** Miscellaneous**Research Type:** Epidemiology Research**Agency** DoD**Study Location** Ft. Detrick**Study Start Date** 4/1/94**Estimated Completion Date** 12/1/98**Project Status** Ongoing**DoD-13****Summary**

OVERALL PROJECT OBJECTIVE: The possibility of exposure to environmental factors and endemic diseases exists for the population of military working dogs (MWDs) that deployed to the Persian Gulf (PG) theater of war. The hypothesis to be tested is that there will be no differences in pathologic diagnoses between the PG MWD cohort and a matched (on basis of age, sex, and breed) comparison group never deployed to Southwest Asia (SWA).

SPECIFIC AIMS: The (null) hypothesis to be tested is that in the final analysis there will be no differences in diagnoses between the PG MWD cohort and the comparison group which never deployed to SWA. Should this hypothesis not be supported: 1) the possibility exists that differences in pathologic diagnoses between the two cohorts may be the result of deployment to SWA; and 2) dates of deployment and location in theater will be compared among the PG MWDs, and conceivably to those of PG veterans.

METHODOLOGY: The PG MWD cohort was identified after the cessation of hostilities and subsequent redeployment. The inclusive deployment dates for this population are 31 July 1990 to 31 December 1991. Generation of data: Those MWDs still living receive semi-annual physical examinations which include routine panels of hematologic, serologic, and chemical analyses; the results of which are posted in their medical records. Those MWDs identified for this study that are euthanized for medical reasons have peripheral blood samples collected for routine blood tests; results of which are included in the dogs permanent medical record. Medical records from all deceased MWDs in the Department of Defense are archived at the DOD Military Working Dog Veterinary Services (DODMWDVS), Lackland Air Force Base, Texas. Those PG cohort MWDs that have been categorized as "not fit for duty" and not humanely euthanized for extenuating medical reasons, may be relocated to the DODMWDVS kennels facilities where the dog will be allowed to live out its natural life span or until a point when euthanasia is elected to prevent or terminate undue suffering. PG cohort MWDs and the comparison group MWDs will undergo a thorough autopsy upon natural death or euthanasia. At autopsy, gross changes are described, and an extensive set of tissues collected and forwarded to the Department of Veterinary Pathology, the Armed Forces Institute of Pathology (AFIP), Washington, DC. The fixed tissues are processed for histologic examination resulting in a final pathology report; the remaining wet tissues, microslides, and case folder materials are archived. Additional fresh tissue specimens of liver, kidney, lung, and adipose tissue are rapidly frozen at the time of autopsy and eventually forwarded to the AFIP for storage until toxicologic analytic procedures may be performed. Antemortem serum samples from all MWDs are banked at the Regional Laboratory, Fort Sam Houston, Texas. Epidemiologic analysis of all data will be accomplished utilizing a master of public health/epidemiology graduate student and a database management system incorporating SNOMED International software coding terminology.

EXPECTED PRODUCTS (MILESTONES): See Objectives.

STATUS/RESULTS TO DATE: Ongoing. We have identified one hundred twenty-four MWDs that deployed to various locations in the PG theater in support of operations within the inclusive dates listed above. The AFIP (American Registry of Pathology) funded a pilot protocol enabling the early implementation of a database system which includes pathologic (including surgical and postmortem morphologic changes), demographic, regional, temporal and clinical findings from initially identified PG MWD cohort and matched comparison MWDs. The pilot protocol funding expired in 1995. The collection and epidemiologic analysis of all available data is the primary responsibility of a US Army Veterinary Corps Officer currently enrolled in a master's of public health/epidemiology

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graduate study program. The project currently has retained the services of a database management systems consultant with expertise in SNOMED International who will follow the development of the DBMS to completion. This DBMS will operate in FOXPRO with an integration of SNOMED, and is expected to be complete in February 1997.

PUBLICATIONS none to date

Title Risk Factors Among US Army Soldiers for Enrolling on the Department of Veterans Affairs Gulf War Registry

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 10/1/93

Estimated Completion Date 9/1/96

Project Status Ongoing

DoD-14

Summary

OVERALL PROJECT OBJECTIVE: Determine the presence of unique characteristics (demographics, aptitude test scores, self-reported health behaviors, past hospitalizations) of Army personnel enrolled in the DVA Registry of Persian Gulf veterans.

SPECIFIC AIMS: The two specific aims of the study are: (1) Investigate logistical, epidemiological, and statistical methodologies for obtaining, combining, and analyzing records. These techniques will be needed for future studies on reported post-deployment illnesses in soldiers who served in the PGW. These techniques would also be applicable in evaluating the health effects of future deployments. (2) Determine which characteristics (to include demographics, past medical history, and health risk behaviors) of soldiers who have been enrolled in the VA PGW registry differ from those who have not enrolled. Ultimately, this information can be used to identify soldiers at a high-risk of reporting post deployment medical problems. These soldiers may be targeted for interventions before or after their deployment to reduce the risk adverse health effects attributable to service in a war zone.

METHODOLOGY: Using case-control methodology we will determine if there is an association between PGW veterans' various demographic, medical, or health behavior characteristics and their probability of enrolling in the PGW registry. Individuals on the VA database and controls from the Defense Manpower Data Center's (DMDC) roster of PGW participants will be the study population. Characteristics evaluated in this hypotheses generating study include demographic factors, recruit applicant aptitude test scores, pre-deployment self-reported health behaviors, and pre-deployment health care utilization as are represented by hospitalizations in military hospitals. These data are available in already existing Army or DoD databases, however, all data may not be available for all study subjects.

EXPECTED PRODUCTS (MILESTONES): (1) A data base of US Army PGW veterans, which includes health indicators and demographic data from the pre, during, and post deployment phases of their military careers. (2) A determination of whether existing data sources can be used to predict a soldier's likelihood of having significant post-deployment adverse health outcomes or a high level of concern about potential health effects of the deployment. This finding will be reported to the military and civilian medical and scientific communities.

STATUS/RESULTS TO DATE: Ongoing. As of March 5, 1996, all databases have been merged and data analysis is underway. Preliminary results should be available within a few months.

PUBLICATIONS none to date

Title Comparative Mortality Among US Military Personnel Worldwide During Operations Desert Shield and Desert Storm

Research Focus: Mortality

Research Type: Epidemiology Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 5/1/94

Estimated Completion Date 1/1/95

Project Status Completed

DoD-15

Summary

OVERALL PROJECT OBJECTIVE: Characterize the disease and non-battle injury (DNBI) mortality experience of US military personnel during ODS/DS. Determine whether US military personnel deployed to Southwest Asia (SWA) had a higher rate of death than US military personnel who did not deploy.

SPECIFIC AIMS: See above objectives.

METHODOLOGY: Casualty reports were used to calculate cause-specific mortality rates among all personnel on active duty in the US Armed Forces (including Reserve and National Guard) over a one-year interval that included the Persian Gulf War. Death rates among active duty personnel deployed to SWA at any time during this period were compared to rates for all military personnel on active duty but not deployed to SWA.

EXPECTED PRODUCTS (MILESTONES): Determination of whether US military personnel deployed to SWA had a higher death rate than non-deployed military personnel.

STATUS/RESULTS TO DATE: Completed. Except for hostile action deaths, the overall mortality experience among US military personnel who deployed to SWA did not significantly differ from that observed among US military personnel who did not deploy to SWA. No evidence of clusters of unexpected deaths were found, except for two accidents. Each death was characterized as to have been most likely caused by disease or trauma. Trauma deaths were additionally classified as due to unintentional (accidental) injury, battle injury, self-inflicted injury, or homicide.

PUBLICATIONS Walter Reed army Institute of Research Report. Comparative Mortality Among US Military Personnel Worldwide During Operations Desert Shield and Desert Storm. January 1995.

Writer JV, DeFraités RF, Brundage JF. Comparative mortality among US military personnel in the Persian Gulf region and worldwide during Operations Desert Shield and Desert Storm. JAMA; 275(2):118-121, 1996.

Title Kuwait Oil Fire Health Risk Assessment

Research Focus: Environmental
Toxicology

Research Type: Applied Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 5/5/91

Estimated Completion Date 2/18/94

Project Status Complete

DoD-16

Summary

OVERALL PROJECT OBJECTIVE: To characterize both the carcinogenic and noncarcinogenic health risks to DOD troops and civilian employees exposed to the environment affected by the oil fires during and after Operation Desert Storm.

SPECIFIC AIMS: 1. Environmental Monitoring. The environmental monitoring study attempted to characterize the concentration of pollutants that DOD personnel were exposed to during their deployment in the Gulf region. Air monitoring and soil sampling data were used to calculate exposure point concentrations for individual Health Risk Assessments in the final report. 2. Industrial Hygiene Sampling Study. The industrial hygiene air survey monitored and characterized occupational exposures of DOD personnel who had potential high risk exposure to oil fire emissions. The focus was on individuals working outdoors and on worst-case situations within the oil fields next to Kuwait City. 3. Biological Surveillance Initiative. The Biological Surveillance Initiative was conducted to refine and corroborate the results from the Health Risk Assessment. This was accomplished by a collection of objective biological measurements of exposure and effect in real-time, and by establishment of any observable biologic effect or marker of exposure to oil fire pollutants in a cohort of U.S. soldiers.

METHODOLOGY: 1. Sampling and Analysis. Sampling and analytical methodologies for ambient air, soil, industrial hygiene air, biologic samples, and quality assurance procedures are detailed in the final report. 2. Risk Assessment. The methodology used for this Health Risk Assessment was the EPA guidance for the Comprehensive Environmental Response, Compensation and Liability Act sites (CERCLA), also known as "Superfund" sites. The methodology did not determine an individual's health outcome or include the use of reported health effects data. The components of the risk assessment process included data collection and evaluation, exposure assessment, toxicity assessment, and risk characterization and uncertainty analysis.

EXPECTED PRODUCTS (MILESTONES): Reports

STATUS/RESULTS TO DATE: Completed. The potential for significant long-term adverse health effects for the exposed DOD troop or civilian employee populations is minimal. The total predicted excess carcinogenic risk both in Kuwait and in Saudi Arabia did not exceed 3 excess cancers per 1,000,000 population exposed. The predicted carcinogenic risk levels are well within the EPA range of acceptable excess carcinogenic risks. The majority (>99%) of noncarcinogenic risk at all monitoring sites is predicted to be from the inhalation of volatile organic compounds and is assessed as low. The results of the Biological Surveillance Initiative support the conclusion that noncarcinogenic risk levels indicate minimal potential adverse health effects.

PUBLICATIONS US Army Environmental Hygiene Agency, Final Report. Kuwait Oil Fire Health Risk Assessment. No. 39-26-L192-91, 18 February 1994.

Title Retrospective Studies Involving Military Use of Pyridostigmine as a Pretreatment for Nerve Agent Poisoning

Research Focus: Pyridostigmine Bromide

Research Type: Epidemiology Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 1/1/91

Estimated Completion Date 5/21/92

Project Status Complete

DoD-17

Summary

OVERALL PROJECT OBJECTIVE: To obtain safety data for New Drug Application with the Food and Drug Administration (FDA).

SPECIFIC AIMS: To perform retrospective evaluation of effects of pyridostigmine use in the Persian Gulf.

METHODOLOGY: Retrospective evaluation.

EXPECTED PRODUCTS (MILESTONES): Reports.

STATUS/RESULTS TO DATE: Complete. Three surveys were completed, reports prepared, and forwarded to the FDA. Results indicated that pyridostigmine continues to be safe. Side effects reported were primarily gastrointestinal in nature. Headaches were also reported by the respondents.

PUBLICATIONS Three Survey Reports consolidated Into an Amendment to the FDA IND Application

Title Kuwait Oil Fires Troop Exposure Assessment Model (TEAM)

Research Focus: Environmental
Toxicology

Research Type: Applied Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 5/31/93

Estimated Completion Date 12/31/96

Project Status Complete

DoD-18

Summary

OVERALL PROJECT OBJECTIVE: To respond to Public Law 102-190 (Section 734: Troop Registry from exposure to oil well fires in Operation Desert Storm) by characterizing the potential carcinogenic and non-carcinogenic health risks to U.S. military personnel exposed to the environment affected by the oil well fires during and after Operation Desert Storm.

SPECIFIC AIMS: The site-specific Kuwait Oil Fire Health Risk Assessment addressed the risks to DOD troops located at the eight fixed air/soil sampling sites where actual environmental data were collected and analyzed. This study will incorporate actual site data with the modeled air concentrations, exposure data, and the Troop Location Registry data, to determine the risk to U.S. military personnel that were not located at fixed sampling sites for their entry tour of duty and for periods of time when no sampling occurred.

METHODOLOGY: Using a geographic information system (GIS) that is capable of mapping troop location and movement over time, in conjunction with the troop movement database, the locations of all US military personnel are being mapped during Operation Desert Storm. Once troop locations have been determined and mapped, the GIS determines troop exposure to oil fire pollution using satellite images, modeled plume boundaries, oil field crude composition data, oil field emission rates, modeled pollutant concentrations, and actual field data. When troop location and exposure have been determined, the potential health risks resulting from the exposure will be determined.

EXPECTED PRODUCTS (MILESTONES): The outcomes expected from this study will be the determination of exposure and potential health risks associated with oil fire pollution for U.S. military personnel participating in Operation Desert Storm.

STATUS/RESULTS TO DATE: This project is ongoing. A majority of the data have been entered into the system. Both satellite plume and modeled plume boundaries (over 270 days, or the February - October 1991 timeframe) have been digitized. Pollutant-specific oil fire emission factors have been derived and integrated into the TEAM; updates on these are on-going. Complete unit identification code location data for the Navy, Marine Corps and Air Force (over 134,000 records) have been entered into the TEAM database. Over 195,000 Army UIC location data are in the TEAM database. The Army UIC location data are incomplete; we expect the final Army UIC location data to be entered into the TEAM database on/about July 26, 1996. In addition, the Desert Storm personnel roster (over 757,000 individuals) are in the TEAM database. We are currently updating the toxicological (from IRIS and HEAST databases) and exposure factor tables of the TEAM database. Over 2,000,000 records have been entered into the TEAM database.

PUBLICATIONS US Army Environmental Hygiene Agency, Final Report. Kuwait Oil Fire Health Risk Assessment. No. 39-26-L192-91, 18 Feb 1994. This report describes the eight fixed air/soil sampling sites study and presents the preliminary results of the KOFTEAM pilot project.

Title Persian Gulf Veterans Health Tracking System**Research Focus:** Environmental
Toxicology**Research Type:** Applied Research**Agency** DoD**Study Location** Ft. Detrick**Study Start Date** 4/1/96**Estimated Completion Date** 12/31/97**Project Status** Ongoing

DoD-19

Summary

OVERALL PROJECT OBJECTIVE: To respond to Public Law 102-585 (Section 702: Scientific research using Troop Health Registry) by characterizing all potential exposures (e.g., oil fires, vaccines, chemical/biological warfare agents, pesticides, pyridostigmine bromide, etc) to U.S. military personnel participating in Operation Desert Storm, and to assess the potential health consequences of those exposures.

SPECIFIC AIMS: The site-specific Kuwait Oil Fire Health Risk Assessment and the Troop Exposure Assessment Model (TEAM) address the potential risks to U.S. military personnel from potential exposure to airborne contaminants from oil well fires. This study attempts to characterize other potential exposures experienced by U.S. military personnel during Operation Desert Storm and to assess the potential health risks/consequences of those potential exposures.

METHODOLOGY: The Persian Gulf Veterans Health Tracking System uses a geographical information system (GIS) to assess potential exposures and medical outcomes for U.S. military personnel who participated in Operation Desert Storm. Once troop locations are determined and mapped (from the Troop Location Registry data), the GIS can help determine potential troop exposure to any number of different chemicals, environmental threats, or other materials. When troop locations and potential exposures have been determined, the potential health risks resulting from the potential exposures can be determined. In addition to examining potential exposure, databases on medical outcomes (e.g., Comprehensive Clinical Evaluation Program, the Veterans Administration Mortality Study, etc.) can be evaluated by studying potential exposures, locations, movements, and relationships of the troops in these databases for epidemiological significance.

EXPECTED PRODUCTS (MILESTONES): Characterization of the potential exposures and health risks/outcomes associated with service by U.S. military personnel in Operation Desert Storm.

STATUS/RESULTS TO DATE: Ongoing. The CCEP database has been integrated into the GIS. Space and time analyses are being performed on the possible low-level chemical agent exposure from munition storage bunker detonations to include the Tall Al Lahm, Hafir Al Batin, and other sites. The soldiers and Units identified in the CCEP, the Environmental Support Group troop unit movement database, and the Defense Manpower Data Center Operation Desert Storm personnel roster are being mapped with respect to their proximity to these sites. Exposure analyses are being performed with dispersion modeling results from the Central Intelligence Agency. We are planning to integrate the chemical detection network data into the GIS for additional low-level chemical agent analyses. In addition, other environmental exposure data sets/databases to include scud sites, tent heaters, microwaves, and dust suppression are being collected and assessed. The CHPPM is expecting to finalize the project database status and methodologies by September 1996.

PUBLICATIONS none to date

Title A Statistical Study Correlating the Reported Cases of Gulf War Syndrome to Battlefield Locations of Afflicted US Army Personnel During the Iraq-Kuwait War; Part 1: Method to Related Troop Deployment and the Reported Cases of Gulf War Syndrome and Probable Incidence of Maladies Defined by ICD-9-CM

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 1/1/94

Estimated Completion Date 7/1/95

Project Status Complete

DoD-20

Summary

OVERALL PROJECT OBJECTIVE: To devise a procedure for counting the collections of symptoms and diagnoses of veterans' illnesses and relating them to the U.S. military grid system locations in the Kuwait-Iraq-Saudi Arabian theater of operations.

SPECIFIC AIMS: To identify the geographic locations by date of the Army personnel who served in the Gulf War and whose names are recorded in the VA register as experiencing severe health problems. The units to which these personnel were assigned are tracked across the Iraq-Kuwait region, in order to determine whether epidemiological commonalities can be detected based upon location at certain dates.

METHODOLOGY: VA malady codes of afflicted personnel related to unit identification codes were identified. Malady information was regrouped and coded into crisp and fuzzy numbers. For the Part 1, only crisp numbered malady information was used. The DOD Register was used to identify geographic coordinate locations of Army units. A mathematical algorithm was developed to compare geographic location to maladies and possible cause(s) of each of the maladies. The algorithm is based on the ratios of the number of combatants reporting illnesses (in any grid) to the total number of combatants (occupying the grid) as discrete probabilities. These are considered to be the probabilities of occurrence of a health condition for the total time period that a military unit occupies a grid. A production model needs to be completed to compute statistical measures that are concerned with Gulf War veterans' illnesses.

EXPECTED PRODUCTS (MILESTONES): A mathematical procedure to count the collections of symptoms and diagnoses over the various map grids of the region.

STATUS/RESULTS TO DATE: Completed.

PUBLICATIONS Army Research Laboratory Technical Report ARL-TR-800, July 1995.

Title Study of Variability In Pyridostigmine Inhibition of Blood Cholinesterases in Healthy Adults and Individuals With Symptoms Following Participation in Operation Desert Storm

Research Focus: Pyridostigmine Bromide **Research Type:** Epidemiology Research

Agency DoD **Study Location** Walter Reed Army MC

Study Start Date 7/11/95 **Estimated Completion Date** 6/30/97

Project Status Ongoing **DoD-21**

Summary

OVERALL PROJECT OBJECTIVE: To determine if individuals have different sensitivities to inhibition of blood cholinesterases by pyridostigmine and/or differences in the rate of spontaneous reactivation of cholinesterases after pyridostigmine exposure. To determine if there is a difference in the cholinesterases of Gulf War veterans who took pyridostigmine and seen at the Gulf War Health Center compared to age and sex matched controls.

METHODOLOGY: Blood (in EDTA) is obtained from Gulf War veterans seen at the Gulf War Health Center at Walter Reed Army Medical Center and from age and sex matched controls. The blood samples are sent to the laboratory at Walter Reed Army Institute of Research (WRAIR) in a blinded fashion. At WRAIR, acetylcholinesterase and butyrylcholinesterase activity is measured. The reactivation time of the enzymes after in vitro exposure to pyridostigmine is also measured.

EXPECTED PRODUCTS (MILESTONES): June 96 Initial results of first 40 volunteers; June 97 Results of 100 volunteers.

STATUS/RESULTS TO DATE: After the blood of the first 20 controls and 20 Gulf War veterans were evaluated by the laboratory, these specimens were unblinded and analyzed. Mean whole blood lysate acetylcholinesterase concentration for all subjects were 5.7 U/ml; mean plasma butyrylcholinesterase concentration was 4.9 U/ml. There was no statistical difference between the controls and the veterans. Reactivation time ($t_{1/2}$ at 5 micromolar pyridostigmine) for all subjects ranged from 29.0 to 45.2 minutes with a mean of 37.0. Mean for veterans and controls were 38.4 and 35.9 minutes, respectively. There was no statistically significant difference between the two groups. As of August 1996, 71 volunteers have entered the study.

In the initial small cohort of volunteers, there was no difference between the enzymatic activity of acetylcholinesterase or butyrylcholinesterase in controls or veterans. There was no difference between the two groups in the reactivation time after in vitro exposure of the blood to pyridostigmine.

PUBLICATIONS In vitro pyridostigmine inhibition of red cell acetylcholinesterase: a comparison in Gulf war veterans and normal controls. 1996 Medical Defense Bioscience Review, Baltimore, Maryland.

Title Chronic Organophosphorus Exposure and Cognition**Research Focus:** Environmental
Toxicology**Research Type:** Basic Research**Agency** DoD**Study Location** Ft. Detrick**Study Start Date** 4/15/95**Estimated Completion Date** 5/14/98**Project Status** Ongoing

DoD-22

Summary

OVERALL PROJECT OBJECTIVE: This study will evaluate the effects of low-level sub-chronic exposure to an organophosphorus cholinesterase inhibitor on normal cognitive function in animal models. The long term goals are to identify the underlying mechanisms of organic brain damage related to environmental toxins and to develop novel treatment strategies to improve memory/cognitive performance in affected patients.

SPECIFIC AIMS: 1. Does low-level sub-chronic exposure to an organophosphorus (OP) cholinesterase inhibitor produce learning or memory deficits in rats and non-human primates trained to perform various memory tasks; and will prior exposure to atropine sensitize animals to atropine sensitize animals to OP agents? 2. Is memory impairment to an OP agent associated with alterations in the presynaptic regulation of cholinergic neurons in relevant brain regions in rats; and/or is there an alteration in the ability of the brain adrenergic system to regulate presynaptic cholinergic function? 3. Is memory impairment to an OP agent associated with alterations in the postsynaptic regulation of cholinergic or adrenergic receptors? Can these alterations be reflected in the genes encoding the various muscarinic or nicotinic receptor subtypes? 4. Can new therapies (reversible cholinesterase inhibitors, nicotinic agonists, adrenergic agonists) which improve memory deficits in Alzheimer's patients also improve cognitive function in rats or monkeys with OP-induced memory impairment?

METHODOLOGY: Protocol 1. Three groups of 12 rats each will be administered 0.25, 0.5, or 1.0 mg/kg of DFP once daily over 2 weeks. The status of brain muscarinic receptors and blood cholinesterase will be determined and 2 days after the last dose of DFP they will be examined for performance in the Morris water maze. Monkeys will be well-trained in the delayed matching-to-sample (DMTS) task. The highest dose of DFP which does not elicit overt signs of anticholinesterase toxicity or which will not decrease DMTS performance will be employed in the study. Protocol 2. Rats will be administered a 14-day DFP regimen. Samples of regional brain tissue will be taken on 4 occasions during treatment from randomly selected rats (6 per time point) to determine the status of choline acetyl transferase (ChAT) activity and for the estimation of ACh turnover rates. We will examine the ability of clonidine to inhibit presynaptic cholinergic function using biochemical techniques. Finally, these experiments will be repeated in rats subjected to atropine sensitization. Protocol 3. Rats will be administered a 14-day DFP regimen. Samples of regional brain tissue will be taken on four occasions during treatment to determine the status of muscarinic, nicotinic, and alpha-adrenergic receptor subtypes in several brain regions using quantitative receptor autoradiography. Small samples of tissue will be removed for quantitative RT-PCR. Protocol 4. The monkeys which have been evaluated in Protocol 1 for production of long-term decrements in DMTS performance will be employed. They will receive increasing doses of drugs designed to enhance cognitive performance. The experiments will occur concomitantly with a similar series performed in rats tested using the Morris water maze.

EXPECTED PRODUCTS (MILESTONES): This research will be dedicated to the elucidation of the mechanism of permanent memory dysfunction produced by exposure to a relevant organophosphorus agent DFP in non-human primate and rat models. Also, we will evaluate the effects of reversing this memory impairment using classical and novel agents developed for patients with Alzheimer's disease.

STATUS/RESULTS TO DATE: Chronic, low-level exposure to acetylcholinesterase (Ache) inhibitor organophosphate (OP) insecticides or chemical warfare agents produces abnormalities in CNS

acetylcholine (ACh) function, and in humans, may be associated with impaired cognitive function well after withdrawal from such exposure. The purpose of the present study was to identify the severity of impairment in spatial learning of rats and monkeys following protracted withdrawal from chronic, low-level exposure to the OP agent diisopropyl fluorophosphate (DFP). Assessment of spatial learning began either 3 or 17 days after completion of a 14 day DFP treatment regimen (50, 250, or 500 mg/kg). During the 14 day treatment regimen, prior to withdrawal, spontaneous activity and olfactory behaviors were initially suppressed during DFP exposure, effects which became tolerant with repeated exposure to the 250 mg/kg dose regimen. Performance of a standard water maze task was impaired for up to 21 days after withdrawal from treatment with a 250 mg/kg dose of DFP. Latencies to find a hidden platform were increased by 30-40% above control levels throughout testing and no overt signs of DFP toxicity were evident. All animals did, however, demonstrate the ability to eventually learn the task. AChE activity in the frontal cortex and hippocampus was suppressed to 41% and 51% of control levels, respectively, after 14 days of DFP (250 mg/kg) treatment. By 7 days after withdrawal from treatment, frontal cortex AChE activity had recovered to 84% of control levels, whereas hippocampal AChE activity had recovered to only 64.40%. By 21 days after withdrawal from treatment, AChE in both brain regions had recovered to near-control levels. Performance of a previously well-learned delayed matching task by monkeys was not affected by DFP regimens after withdrawal of the drug. Chronic, low-level OP exposure, therefore, produces protracted impairment of working memory after drug withdrawal that is not associated with continue suppression of AChE activity. This impairment may be attributed to the decrease in recovery of AChE in the hippocampus, relative to the cortex. This decreased rate of enzyme recovery may contribute to hippocampal toxicity underlying protracted impairment of working memory. In 3 rhesus monkeys well trained in the performance of a delayed response task, chronic daily exposure to 10-20 mg/kg of DFP produced severe toxicity and task impairment after 8 weeks of treatment. However, task performance was at near control levels by 6-10 days after DFP withdrawal. Withdrawal from chronic exposure to low levels of DFP may compromise working memory or learning of a new task, but fails to inhibit the performance of a well learned task if no toxicity is present.

Celastrus paniculatus (CP), a medicinal plant from India has been reputed to be useful as a pharmaceutical aid for learning and memory. We investigated the effects of the seed oil of CP on the 6 day performance of young adult rats in a navigational memory task. Chronic oral (gavage) daily treatment with CP, (50, 200, or 400 mg/kg) for 14 days completely reversed the scopolamine (0.5 mg/kg)-induced task performance deficit. Acute treatment or chronic 14 day treatment with CP resulted in no significant alteration in normal locomotor activity in an open field. Moreover, CP did not alter the scopolamine-induced increases in horizontal locomotor activity. Chronic treatment with CP did not alter brain acetylcholinesterase levels and no signs of cholinergic overstimulation were ever noted during or after treatment. Thus, the seed oil of CP, when administered chronically, selectively reversed the impairment in spatial memory produced by acute central muscarinic receptor blockage, supporting the possibility that one or more constituents of the oil may offer cognitive enhancing properties. CP may be more effective in individuals who are cognitively impaired as a result of chemical or organic brain damage as compared with normal subjects.

PUBLICATIONS none to date

Title Acute and Long-Term Impact of Deployment to Southwest Asia on the Physical and Mental Health of Soldiers and their Families

Research Focus: Brain & Nervous System

Research Type: Epidemiology Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 10/1/93

Estimated Completion Date 9/1/98

Project Status Ongoing

DoD-23

Summary

OVERALL PROJECT OBJECTIVE: Determine the acute and long-term impact of deployment to SWA on the physical and mental health of soldiers and their families.

SPECIFIC AIMS: Determine the acute and long-term impact of deployment to SWA on the physical and mental health of soldiers organizational, and environmental factors within military units that produce psychiatric casualties. Identify the critical indicators resulting in increased risk and assess the long-term consequences of exposure to trauma. Develop recommendations on post-deployment interventions. Determine impacts of Army family support policies and programs on active duty and reserve component soldiers and their families.

METHODOLOGY: Interviews and surveys of soldiers and leaders participating in ODS were conducted several times prior to the ground war, immediately after the ground war, and at intervals following return home. Soldiers and their spouses were surveyed and interviewed in order to evaluate the social, psychological, organizational, and environmental factors within military units that produce psychiatric casualties, lead to dysfunctional behavior and decrements in military performance, generate psychomatic illness and increased susceptibility to physical illness. The family-community research team performed field surveys of spouses of active duty and reserve component (USAR) and (ARNG) soldiers from units deployed to the Persian Gulf for ODS on deployment-related stressors and psychological symptoms, spouse support-seeking behavior, family perceptions of Army support and assistance, stress-coping responses, and family well-being during reunion with returning soldiers and in the aftermath of ODS. Surveys and interviews of selected Reserve and National Guard units and their families have been conducted during the period following ODS, while additional interviews and surveys were conducted with soldiers and families participating in Operation Just Cause and Sinai peacekeeping deployments.

EXPECTED PRODUCTS (MILESTONES): Develop recommendations affecting post-combat interventions. Determine the impact of Army family support policies and programs on both active duty and research component soldiers and families.

STATUS/RESULTS TO DATE: Ongoing. An assessment of psychological factors related to deployment stress and family separation during Operation Desert Shield/Storm was conducted with a stratified sample of married and single U.S. Army Individual Ready Reserve soldiers two years post ODS. Analyses were performed in 1994 with final report completed in spring of 1995. Report submitted to Army Deputy Chief of Staff for Personnel. Deployment stress and adaptation was studied on a large sample of U.S. Army National Guard and U.S. Army Reserve Unit (TPU) soldiers who activated and deployed for Operation Desert Shield/Storm. Physiological stress, distress, coping and factors related to current deployed effects of family separation were assessed. Physiological well-being was studied with respect to deployment location factors. Persian Gulf Region analyses were performed in summer of 1995 and resulted in a manuscript on the long term effects of Desert Storm on the Army Reserve and National Guard soldiers and their families.

PUBLICATIONS Epidemiological considerations regarding the health and effectiveness of women in the armed forces. Technical Report, AD#ADA278202.

Combat service support survey results: A light infantry division and a mechanized infantry division. Technical Report AD#ADA278203.

The Long Term Effects of Operation Desert Storm on the Psychological Well-Being of U.S. Army Reserve and National Guard Veterans. Manuscript under

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review by editors of J Applied Social Psychology.

Title Epidemiological Studies Persian Gulf War Illnesses, PG Women's Health Linkage Study

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency DoD

Study Location Washington

Study Start Date 6/1/96

Estimated Completion Date 1/31/99

Project Status Ongoing

DoD-30

Summary

OVERALL PROJECT OBJECTIVE: This research addresses the effects of Gulf War service on military women's health. The studies will compare the incidence, prevalence, general health outcomes, and risks of women deployed in the Gulf War theater of operations with Gulf War era women who were not deployed to the Gulf.

SPECIFIC AIMS: Linkage of exposure to outcomes. Health outcomes of women who served in the Persian Gulf War.

METHODOLOGY: Self-reported survey linked to Persian Gulf tracking file and other mapping files.

EXPECTED PRODUCTS (MILESTONES): Reports and publications.

STATUS/RESULTS TO DATE: Ongoing. Questionnaires to OMB in late fall of 1996. Met with Director U.S. Army and Joint Services Environmental Support Group.

PUBLICATIONS none to date

Title Dysregulation of the Stress Response in the Persian Gulf Syndrome

Research Focus: Brain & Nervous System

Research Type: Epidemiology/Clinical Research

Agency DoD

Study Location Washington, DC

Study Start Date 5/6/96

Estimated Completion Date 6/6/99

Project Status Ongoing

DoD-31

Summary

OVERALL PROJECT OBJECTIVE: The purpose of this study is to demonstrate that objective neurohormonal abnormalities in the human 'stress response' are present in Gulf War veterans with unexplained multiple symptoms similar to fibromyalgia, chronic fatigue syndrome, somatoform disorder, multiple chemical sensitivity and that these neurohormonal abnormalities are at least partly responsible for these symptoms. There are several axes of the stress response which can independently or concurrently function aberrantly in these conditions, including the autonomic nervous system, the hypothalamic-pituitary axes, and descending anti-nociceptive pathways. Specific symptomatology results when each of these systems functions improperly.

SPECIFIC AIMS: In this study the investigators propose to demonstrate that:

- a. Gulf War veterans with undiagnosed symptoms display centrally mediated disturbances in autonomic tone, and this leads to vasomotor instability and smooth muscle dysmotility, and symptoms such as irritable bowel syndrome, and migraine headaches.
- b. Gulf War veterans with undiagnosed symptoms display diffuse disturbances in nociception (pain threshold) that are partly responsible for many of the pain-related symptoms seen in this condition (e.g., myalgia, arthralgia, sore throat).
- c. The same neuroendocrine changes seen in fibromyalgia, chronic fatigue syndrome, and post-traumatic stress syndrome, characterized by blunting of the hypothalamic-pituitary axes, are seen in Gulf War veterans with undiagnosed symptoms, and contribute substantially to the fatigue seen in this condition.

METHODS: Each of these hypotheses will be tested in a multidisciplinary study which involves a collaborative effort between Georgetown University Medical Center, the Washington D.C. VA Medical Center (a specialized care center for Gulf War veterans) and consultants from the National Institutes of Health. The demonstration of common underlying pathophysiologic mechanisms in fibromyalgia, chronic fatigue syndrome, multiple chemical sensitivity and the undiagnosed illnesses of Gulf War veterans will be tremendously beneficial. This research should lead to both more effective treatment of these individuals and perhaps effective strategies to avoid these problems in future deployments.

EXPECTED PRODUCTS (MILESTONES):

STATUS/RESULTS TO DATE:

PUBLICATIONS none to date

Title Neuropsychological Functioning in Persian Gulf Era Veterans

Research Focus: Brain & Nervous System

Research Type: Epidemiology/Clinical Research

Agency DoD

Study Location VAMC Boston, MA

Study Start Date 5/1/96

Estimated Completion Date 5/1/99

Project Status Ongoing

DoD-32

Summary

OVERALL PROJECT OBJECTIVE: To evaluate the neuropsychological functioning of PGW-era veterans who are seeking treatment or diagnostic evaluation for any type of health or adjustment complaint. The group of patients who were deployed to the Gulf are being compared to a treatment seeking patient group who were not deployed to the Gulf. Data from these groups are also being compared with those from a (non-treatment seeking) research sample of PGW veterans who are being studied using the same neuropsychological instruments. In addition, all of these patients and research subjects are being administered a standardized set of questionnaires and semi-structured interviews that will identify their current health symptoms, pre-existing physical and mental health condition, sociodemographic variables, Gulf experiences, and Post PGW-era stressors. These instruments also permit PTSD, MCS, CFS, and other psychiatric disorders to be diagnosed.

SPECIFIC AIMS: The specific aim of this study is to determine whether veterans of the Persian Gulf War (PGW) show cognitive impairments suggestive of central nervous system damage at a greater rate than PGW-era veterans who were not deployed to the Gulf.

METHODOLOGY: Two hundred subjects will be examined in three years; 100 veterans deployed to the Gulf during the PGW and 100 serving in the military during that era who were not deployed to the Gulf. These subjects will be recruited from among those seeking treatment or diagnostic evaluation at the Boston VAMC through all outpatient treatment services. It is anticipated that approximately 40 subjects in each group will be recruited in each of years 1 and 2, and 20 in each group in year 3 of the proposed period of support. The recruitment procedure has been fully outlined. It has been devised to reduce selection bias that would reduce the comparability of Gulf-deployed and non-deployed veterans.

a. **Subjects.** All treatment seeking veterans discharged from the military since the beginning of the PGW will be considered potential subjects. A list of veterans who have been admitted to any outpatient clinical service (with the exclusion of the substance abuse clinic) at the Boston VAMC in Jamaica Plain, the outpatient clinic at Causeway Street, and the Lowell VAMC will be generated by the supervisor of outpatient clinics and will be updated periodically. This list will include names, social security numbers, and telephone numbers (where available) or addresses (if telephone numbers are not available). As a preliminary step, the lists will be cross-checked with the Persian Gulf War Registry to determine the approximate proportions of the PGW veterans and non-deployed PGW-era veterans available. However, the personnel involved in the recruitment of subjects will not be aware of the status of potential subjects with regard to deployment to the Gulf and steps will be taken to reduce the likelihood that this information will become known to project staff during the recruitment process.

b. **Initial Contact.** The first contact with potential subjects will be by telephone (or by mail, if there is no telephone number available). At the beginning of this contact, subjects will be requested to not indicate whether or not they served in the Gulf. They will be told that, if they should decide to participate in the research project, information concerning deployment will be obtained at a later time. The initial contact will consist of a description of the project, including types of assessment, time required, and financial compensation. Subjects will have an opportunity to ask questions about the procedure. They will be informed that whether or not they participate will have no bearing on their medical care and that, if they choose to participate, that they may withdraw at any time without prejudice. They will be asked to indicate whether they wish to participate, wish not to participate, or wish to defer this decision. An appointment at the Boston VAMC will be scheduled for

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patients agreeing to participate.

c. Methods. Patients will first be seen for a brief screening interview and patients retained in the study sample will be presented the study consent form for signature. Subjects will complete a battery of neuropsychological tests, a set of questionnaires, and 2 semi-structured interviews (one will encompass their current health and past environmental exposure history; the other will be done to determine psychiatric and/or PTSD diagnoses).

EXPECTED PRODUCTS (MILESTONES): To isolate factors that may differentiate those who served in the Gulf who are seeking treatment for health complaints from their treatment-seeking counterparts who were not deployed to the Gulf. This is a step toward understanding the Gulf War Syndrome.

STATUS/RESULTS TO DATE: Potential subjects have been identified from database of outpatients seeking treatment and subject recruitment is currently proceeding.

PUBLICATIONS none to date

Title Effects of Pyridostigmine in Flinders Line Rats Differing in Cholinergic Sensitivity

Research Focus: Pyridostigmine Bromide

Research Type: Basic Research

Agency DoD

Study Location Chapel Hill, NC

Study Start Date 7/1/96

Estimated Completion Date 6/30/98

Project Status Ongoing

DoD-33

Summary

OVERALL PROJECT OBJECTIVE: Demonstrate that there are strain differences in the acute effects of pyridostigmine and the ability of chronic pyridostigmine to protect against other anticholinesterase agents.

SPECIFIC AIMS: Determine strain-dependent effects of acute and chronically administered pyridostigmine; determine whether chronic pyridostigmine will protect agonists effects of other anticholinesterase agents.

METHODOLOGY: Rats will be treated with pyridostigmine acutely or chronically and growth hormone, body temperature and locomotor activity will be assessed.

EXPECTED PRODUCTS/MILESTONES: Development of challenge to predict cholinergic sensitivity in soldiers.

STATUS/RESULTS TO DATE: Animals being bred, materials ordered.

PUBLICATIONS none to date

Title Characterization of Emissions from Heaters Burning Leaded Diesel Fuel in Unvented Tents

Research Focus: Environmental
Toxicology

Research Type: Applied Research

Agency DoD

Study Location Albuquerque, NM

Study Start Date 6/7/96

Estimated Completion Date 7/6/98

Project Status Ongoing

DoD-34

Summary

OVERALL PROJECT OBJECTIVE: To conduct a study that simulates human exposure to aerosols in invented tents heated by leaded diesel fuel, with the tent and fuel composition similar to those used in the Persian Gulf, so that the contribution of exposure to this in-tent pollutant can be estimated.

SPECIFIC AIMS: 1) Physical and chemical characterization of aerosols produced by heaters that burned leaded diesel fuel in an unvented tent; and, 2) Estimation of exposure to lead, combustion gases (such as CO₂, CO, NO_x, and SO₂), and organic compounds (such as PAHs).

METHODOLOGY: The tent and heaters will be obtained from the Army, and four heaters will be evaluated for variability. Aerosols and vapors will be characterized physically and chemically using a Tenax sampler (vapors), the Lovelace Multi-jet Cascade Impactor/Parallel Flow Diffusion Battery (aerosol size distribution, concentration, and chemical composition vs. particle sizes), an electrostatic precipitator sampler (particle morphology), and filter samples (aerosol concentration). These samples will provide chemical compositions, lead content, time-averaged aerosol size distribution, and concentration. Real-time aerosol size distribution and concentration as a function of time will be obtained using a Quartz Crystal Microbalance or a Differential Mobility Particle Sizer.

EXPECTED PRODUCTS/MILESTONES: This research will provide detailed information on pollutants produced in unvented tents from heaters that burn leaded diesel fuels. This information is needed to assess potential exposure of service personnel who served in the Persian Gulf War.

STATUS/RESULTS TO DATE: We are still unable to obtain (or purchase) the needed tent, heaters, and fuels used in the Persian Gulf from the Army. We are preparing the research protocol for the project. Currently the protocol is under the institutional approval process.

PUBLICATIONS none to date

Title Feasibility of Investigating Whether There is a Relationship Between Birth Defects and Service in the Gulf War.

Research Focus: Reproductive Health
Studies

Research Type: Epidemiology Research

Agency DoD

Study Location Sacramento, CA

Study Start Date 6/1/96

Estimated Completion Date 6/30/98

Project Status Ongoing

DoD-35

Summary

OVERALL PROJECT OBJECTIVE: To determine whether Reserve participants in the Persian Gulf War can be linked to vital statistics and Birth Defects Registry data.

SPECIFIC AIMS: 1) To determine if DoD computerized information is accurate compared to the hospital medical records and, 2) to determine the feasibility of investigating birth defects in the children of the Persian Gulf War veterans; and, 3) to answer the research questions.

STATUS/RESULTS TO DATE: Unable to begin due to delays by Army HSRRB to approve a necessary waiver.

PUBLICATIONS none to date

Title Fatigue in Persian Gulf Syndrome-Physiologic Mechanisms

Research Focus: Brain & Nervous System

Research Type: Epidemiology/Clinical Research

Agency DoD

Study Location Dallas, TX

Study Start Date 6/15/96

Estimated Completion Date 7/14/98

Project Status Ongoing

DoD-36

Summary

OVERALL PROJECT OBJECTIVE: This research addresses the symptom of abnormal fatigue in Gulf War veterans. The study will examine the possibility that mechanisms used by muscle cells to use oxygen and produce energy for work may be impaired in patients suffering abnormal muscle fatigue and the inability to exercise.

SPECIFIC AIMS: On the basis of preliminary results of evaluation of symptoms of abnormal fatigability in Gulf War veterans, the researchers hypothesize that the common complaint of abnormal fatigue and exercise intolerance in these patients is attributable to impaired energy production via oxidative phosphorylation. Under this general hypothesis, the researcher will address four specific question: (1) Is there an abnormality in muscle oxygen utilization or oxygen transport to muscle during exercise in affected individuals? (2) Is there exaggerated metabolic muscle fatigue in exercise consistent with impaired energy production? (3) Is the metabolic and physiologic response to aerobic physical conditioning impaired in these patients? (4) Is there a specific pattern of impaired activities of mitochondrial oxidative enzymes or respiratory chain complexes to account for impaired oxidative metabolism on attenuated increases in oxidative capacity in response to physical training.

METHODOLOGY: To answer these questions the researchers will employ forearm and cycle exercise to determine maximal work and oxidative capacity and to compare fatigue and metabolic responses to similar workloads among patients and age- and weight-matched sedentary control subjects. The study will compare muscle metabolic and physiologic responses to aerobic training in patients and matched control subjects. The oxidative mechanism in blood will be monitored by measurements of blood levels of diffusible metabolites that reflect oxidative capacity; measurement of intramuscular metabolites using ³¹-phosphorus magnetic resonance spectroscopy; and by using infrared spectroscopy. A cohort of patients and control subjects will be used to evaluate the hypothesis that oxidative limitations detected with non-invasive testing is attributable to impaired function of the mitochondrial respiratory chain as assessed biochemically in biopsied muscle. Exercise protocols and non-invasive monitors of oxygen transport and utilization as well as detailed muscle biochemistry will be used to identify specific causes of exercise intolerance in patients.

EXPECTED PRODUCTS (MILESTONES):

STATUS/RESULTS TO DATE:

PUBLICATIONS none to date

Title Neurobehavioral and Immunological Toxicity of Pyridostigmine, Permethrin, and DEET in Male and Female Rats

Research Focus: Pyridostigmine Bromide

Research Type: Basic Research

Agency DoD

Study Location Gainesville, FL

Study Start Date 5/1/96

Estimated Completion Date 6/1/99

Project Status Ongoing

DoD-37

Summary

OVERALL PROJECT OBJECTIVE: To determine effects of small doses, alone or in combination, in males and females. This multidisciplinary study using male and females rats will examine any neurobehavioral toxicity and immune response alterations after exposure to pyridostigmine bromide, permethrin and DEET alone and in combinations. Human lymphocyte cells will also be studied for inhibition of immune response as a result of exposures to these materials.

SPECIFIC AIMS: The main hypothesis of this multidisciplinary study is that the administration of pyridostigmine bromide (PB), permethrin (PERM) and DEET as single agents, or in combination, results in neurobehavioral toxicity and an altered immune response. Furthermore, it is believed that females are significantly more sensitive to the effects of these agents than are males. To evaluate this hypothesis, experiments have been designed to measure various aspects of CNS functioning in the presence of sub-toxic doses of PB, PERM, and DEET in adult male and female rats. Doses for PB will be 3/10/30 mg/kg, for PERM will be 15/30/60 mg/kg and for DEET will be 50/200/500 mg/kg. In addition, plasma concentrations of PB, PERM, and DEET will be determined and their effects on cholinesterase activity will be correlated with CNS functioning. The neurobehavioral analyses will be complemented by an assessment of the immune response in the same subjects, as well in lymphocytes from health human volunteers.

The neurobehavioral test battery is designed to measure critical aspects of CNS functioning related to symptoms of generalized fatigue, gastro-intestinal disturbance, muscle and joint pain, headaches, and memory loss. The neurobehavioral test battery includes an assessment of spontaneous locomotor behavior and an analysis of overall CNS functioning, motivation and memory performance. This study extends observations from previous experiments in male rats exposed to toxic doses of pyridostigmine or permethrin to female rats and to the effects of PB, permethrin and/or DEET in combination. This study will also provide additional information on the motivational and memory aspects of CNS functioning.

METHODOLOGY: Chemical analyses will determine (1) the metabolism and elimination of PB, permethrin and DEET, alone and in combination, for male and female subjects who participated in the neurobehavioral experiments, and (2) how PB, permethrin and DEET, alone and in combination, affect cholinesterase activity in these same subjects. This information will allow the correlation of plasma concentrations of PB, permethrin and DEET with the behavioral observations.

EXPECTED PRODUCTS (MILESTONES): The immunological experiments will be conducted to determine the role of PB, permethrin and DEET and (1) Suppression of the first and second signal transduction pathways in T-lymphocytes, (2) Cytokine expression, and (3) B-lymphocyte function.

STATUS/RESULTS TO DATE: Project started 5/5/96; initial experiment just under way.

PUBLICATIONS none to date

Title Diagnostic Antigens of *Leishmania tropica*

Research Focus: Leishmaniasis

Research Type: Applied Research

Agency DoD

Study Location Seattle, WA

Study Start Date 6/1/96

Estimated Completion Date 5/31/98

Project Status Ongoing

DoD-38

Summary

OVERALL PROJECT OBJECTIVE: This research will attempt to develop a sensitive method to detect infection with *Leishmania tropica*, or related species, in military personnel.

SPECIFIC AIMS: There are currently no defined antigens for use in the diagnosis of leishmaniasis. There is an urgent need for sensitive methods to detect infection with *Leishmania tropica*, or related species, in military personnel. The researchers have developed such tests for other *Leishmania* species, and have isolated and characterized *L. tropica* antigens reactive with sera from *L. tropica* infected Gulf War veterans.

This study will attempt to develop similar tests for *L. tropica* using these recombinant *L. tropica* antigens. Effort will also be directed at cloning additional *L. tropica* antigens reactive with *L. tropica* infection sera and antigens that stimulate T-cells from individuals with *L. tropica* infection.

METHODOLOGY: Emphasis will be given to expressed genes which are highly sensitive. Inserts will be sequenced for determination of epitopes which may be produced synthetically. Recombinant or synthetic peptides will be evaluated by ELISA for their ability to detect antibody in patient sera. In related studies, cloned gene products will be evaluated for their ability to elicit patient T-cell response in vitro. These evaluations will include proliferation and cytokine production. Emphasis will be placed on finding antigens which are shared between *Leishmania* species having the ability to elicit strong T-cell responses. Such antigens will be candidates for skin test antigens and vaccine production.

EXPECTED PRODUCTS (MILESTONES):

STATUS/RESULTS TO DATE: Several new peptides of Lt-1 antigen have been made and evaluated them as serological reagents. Also, screening of *L. tropica* genomic libraries for new antigens have begun.

PUBLICATIONS none to date

Title A Controlled Epidemiological and Clinical Study into the Effect of Gulf War Service on Servicemen and Women of the United Kingdom Armed Forces

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency DoD

Study Location London, England

Study Start Date 6/1/96

Estimated Completion Date 6/30/99

Project Status Ongoing

DoD-39

Summary

OVERALL PROJECT OBJECTIVE: This research addresses the prevalence of unexplained illnesses, including chronic fatigue-like symptoms, in members of the United Kingdom Armed Forces who were deployed to the Persian Gulf during the Gulf War and who have served, and are serving in Bosnia.

SPECIFIC AIMS: This study is a two stage cohort study. Stage 1 consists of a postal health screening questionnaire to be sent to three groups who were/are in the Armed Forces; those who served in the Persian Gulf, those who served in Bosnia, and those who served in neither the Persian Gulf or Bosnia. The second stage involves performing neuropsychological tests on cases identified by stage 1 and a control group.

METHODOLOGY: This epidemiological study of the prevalence of unexplained illnesses in the populations at risk will use a two-stage design. Stage 1 will be a questionnaire survey of 3000 Gulf War veterans selected at random, an equivalent sample of Bosnia veterans, and appropriate control groups for each. Stage II will involve interview, examination, and testing of all those (approximately 10%) in Stage I who fall above a cutoff defining subjective health. Information gathered at Stage II will be used to estimate the prevalence of diagnosed and unexplained morbidity, including chronic fatigue symptoms, in UK service personnel, and to calculate whether there is an excess associated with Gulf War and/or Bosnia service. If there is, then the researchers will be able to examine pre-morbid and psychosocial factors which may be implicated in such an increase, as well as identify avenues for further biological and psychosocial research.

This epidemiological study should ascertain if service in the Gulf War by UK armed forces personnel was associated with an increase in physical and/or psychological morbidity, and if so, if there is evidence of an increase in either new or ill-defined conditions such as chronic fatigue syndrome, or an illness peculiar to Gulf War service.

EXPECTED PRODUCTS (MILESTONES): Reports and publications.

STATUS/RESULTS TO DATE: Project at the questionnaire design stage.

PUBLICATIONS none to date

Title Psychological and Neurobiological Consequences of the Gulf War Experience

Research Focus: Brain & Nervous System

Research Type: Epidemiology/Clinical Research

Agency DoD

Study Location VAMC West Haven, CT

Study Start Date 6/7/96

Estimated Completion Date 7/6/99

Project Status Ongoing

DoD-40

Summary

OVERALL PROJECT OBJECTIVE: To determine the nature of memory for traumatic events as they relate to PTSD symptomatology.

SPECIFIC AIMS: To examine the course of memory for traumatic events over time and the brain areas believed to be altered due to trauma.

METHODOLOGY: Longitudinal follow-up of a cohort of veterans of Operation Desert Storm (e.g. questionnaires, ratings scales). MRI study of 30 Desert Storm veterans with PTSD. This research will continue to follow the course of symptoms of Post-Traumatic Stress Disorder in a population of Gulf War veterans. This study of how such symptoms, as well as memory function, change over time in the veterans will lead to a better understanding of PTSD and the elements of risk that would cause and continue PTSD symptoms over time.

The study is in two parts. The first part is a longitudinal descriptive study of trauma-related symptomatology in Gulf War veterans. The second part is an investigation of memory function and hippocampal volume in Gulf War veterans who meet criteria for post-traumatic stress disorder (PTSD). Results of the researchers' previous work with a cohort of Gulf War veterans indicated that there was an overall increase in PTSD symptomatology in the veterans over the first two years following the Gulf War. With regard to memory testing, there were many instances of inconsistent recall for events that were objective and highly traumatic in nature. The data do not support the position that traumatic memories are fixed or indelible and suggest that as PTSD symptomatology increases, so does amplification of memory for traumatic events.

This study continues the original methodology for the fifth, sixth and seventh post-war years. It is anticipated that a high percentage of subjects who have already participated in this research can be recruited to continue in this project and that at least 100 new subjects can also be recruited. It is anticipated that a better understanding of the longitudinal course of trauma-related symptomatology and risk factors for the development and maintenance of these symptoms would have implications for treatment.

The second part of the study will examine the possibility that memory deficits in the subject population are relatively broad-based and reflect problems at several levels of information processing, including acquisition, retention and/or retrieval and that these memory deficits may be related to decreased hippocampal volume. Results of this study would make it possible to determine whether these abnormalities are present in a variety of combat populations and whether such abnormalities can be detected at earlier stages than in the previously-studied Vietnam veteran population. Potential relationship to clinical symptomatology and psychosocial functioning will also be investigated.

EXPECTED PRODUCTS/MILESTONES: We expect to show that memory for traumatic events is not consistent over time, and that there may be associated decrease in hippocampal volume in PTSD.

STATUS/RESULTS TO DATE:

PUBLICATIONS none to date

Title Evaluation of Muscle Function in Persian Gulf Veterans**Research Focus:** Brain & Nervous System**Research Type:** Epidemiology/Clinical Research**Agency** DoD**Study Location** Philadelphia, PA**Study Start Date** 6/15/96**Estimated Completion Date** 11/14/99**Project Status** Ongoing**DoD-41****Summary**

OVERALL PROJECT OBJECTIVE: The major objective of this research is to investigate the etiology response for the ongoing chronic fatigue and muscle weakness in Gulf War veterans with unexplained illnesses by evaluating abnormalities in skeletal muscle function in Gulf War veterans. **SPECIFIC AIMS:** 1. To evaluate skeletal muscle in Persian Gulf veterans with severe chronic fatigue and Persian Gulf veterans with no medical complaints (healthy controls); 2. To determine the relationship between the severity of chronic fatigue in Persian Gulf veterans and the degree of muscle dysfunction; 3. To compare muscle function in Persian Gulf veterans with severe chronic fatigue with muscle function in healthy sedentary civilians and civilians with chronic fatigue.

METHODOLOGY: The goal of this proposal is to evaluate skeletal muscle in Persian Gulf veterans. Our major hypothesis is that Persian Gulf veterans who present a symptom profile consistent with chronic fatigue suffer from muscle dysfunctioning. In addition, we hypothesize that the severity of chronic fatigue in this population is related to the degree of muscle dysfunctioning. To test these hypotheses, a battery of tests will be performed on Persian Gulf veterans with severe chronic fatigue (n=50) and on Persian Gulf veterans who were deployed but who have no medical problems (n=50). The evaluation will consist of the following measurements: 1. Functional assessment as reflected in isometric and isokinetic measures; 2. In vivo metabolic measures as determined by ³¹P-Magnetic Resonance spectroscopy (MRS); 3. In vivo morphological measures as determined via Magnetic Resonance Imaging (MRI); 4. Histological analyses of muscle biopsies; 5. Electromyographic evaluation of motor unit recruitment; 6. Muscle enzyme levels; 7. Genetic screening.

EXPECTED PROJECTS (MILESTONES): This project runs over three years. The first 6 months serve to recruit the subjects and to train the necessary personnel. The following two years will be used to collect all the data at a rate of approximately 1 subject/week. So that at the end of the first year we will have tested 13 Persian Gulf veterans with chronic fatigue and 13 healthy veterans. At the end of the second year, we should have tested another 24 subjects with chronic fatigue and 24 healthy controls. For the first 6 months of the third year we will test the final 13 veterans with chronic fatigue and 13 controls, so that the data collection will be completed at the end of 2.5 years. The final 6 months of this 3 year period will be used to analyze and interpret the data, to disseminate the results to the Department of Defense and the veteran community, and to write scientific papers.

STATUS/RESULTS TO DATE: Recruiting of subjects has been started, necessary personnel is being trained.

PUBLICATIONS none to date

Title The Symptomatic Persian Gulf Veterans Protocol: An Analysis of Risk Factors with an Immunologic and Neuropsychiatric Assessment

Research Focus: Symptoms/General Health

Research Type: Epidemiology/Clinical Research

Agency DoD

Study Location VAMC Birmingham

Study Start Date

Estimated Completion Date

Project Status Pending Funding

DoD-42

Summary

OVERALL PROJECT OBJECTIVE: Soon after the resolution of the Persian Gulf War, veterans were seen with a variety of complaints alleged to be related to the conflict. Many of the complaints were vague and relatively non-specific (i.e. myalgias, arthralgias, headaches or memory loss). However, in association with intense media publicity, the term Persian Gulf War syndrome was coined. Attempts to define a specific clinical spectrum seen in this 'disorder' have not been successful. Nonetheless, a number of potential causes have been discussed and include exposures to organophosphates, pyridostigmine, petrochemical combustion products, depleted uranium from projectiles and exposure to a variety of endemic infectious agents including leishmania and mycoplasma. There are a few isolated reports of identification in the urine of organisms from symptomatic veterans and treatment successes with long term antibiotics or demonstration of genetic material from mycoplasma in blood of symptomatic veterans. It is not clear from these reports that such studies have been adequately controlled, nor have they been replicated.

Additionally, based on complaints such as fatigue and memory loss, it has been speculated that there may be neuropsychiatric abnormalities responsible for many of the complaints seen in veterans returning from the Persian Gulf war.

However, at this time, there is little compelling evidence that any of these are major factors in the majority of symptomatic Persian Gulf veterans. At this point it is not even clear that veterans from the Gulf War have different symptoms than patients from other conflicts or for that matter, civilians without military service.

The Birmingham VAMC has been very active in evaluating patients returning from the Persian Gulf war. Approximately 1400 individuals have been seen and have had evaluations. Of these, about 10-15% are asymptomatic. Of the remaining 85%, approximately 90% have a diagnosable illness.

Clearly, it is important to define the spectrum of their illnesses and determine factors which may be contributing to the development of their symptoms. Additionally, a number of Persian Gulf veterans, which we estimate conservatively as 100 of those seen at the BVAMC, are symptomatic and do not have defined illnesses. An adequately controlled study investigating veterans who have an undiagnosed illness to determine if there are fundamental neuropsychiatric or immunologic abnormalities would be important in either validating claims or allaying fears regarding postulates of abnormalities in these areas. To answer these questions, we propose a case control format.

SPECIFIC AIMS: The specific goals of this proposal are to:

1) evaluate self-reported conditions in Persian Gulf veterans to determine if they represent described and accepted medical conditions and/or are associated with objective findings which would validate these symptoms.

2) evaluate symptomatic Gulf war veterans to determine risk factors which may identify veterans who have reported symptoms.

3) evaluate in a controlled fashion symptomatic, but undiagnosed, Persian Gulf war veterans to determine if there is a definable immunologic or neuro-psychiatric abnormality.

METHODOLOGY: This study will determine whether specific immunological or neuropsychiatric abnormalities can be detected in GW participants who are symptomatic, but in whom no specific diagnosis has as yet been made. These studies may uncover an immunological basis for some of the broad types of symptoms reported by GW veterans. This proposal attempts to get at the heart of the problem cited in the Institute of Medicine (IOM) report that GW veterans' mystery illnesses

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may not be a single illness and that it is important to study various possible causes and the interactions between causes. This work will build upon previous work and local programs. The use of advanced methodology in the imaging, immune, mycoplasma and oxidant injury study is important. Sample sizes are adequate and support for statistical analysis is an integral part of the proposal.

EXPECTED PRODUCTS (MILESTONES): Reports and publications.

STATUS/RESULTS TO DATE: This study has not been awarded yet, therefore, there is no start or estimated completion dates.

PUBLICATIONS none to date

Title Investigation of Seminal Plasma Hypersensitivity Reactions

Research Focus: Reproductive Health
Studies

Research Type: Epidemiology/Clinical Research

Agency DoD

Study Location Univ. Cincinnati MSC

Study Start Date 11/1/96

Estimated Completion Date 10/1/99

Project Status Pending Funding

DoD-44

Summary

OVERALL PROJECT OBJECTIVE: This study is a coordinated effort to determine whether the Gulf War vaginal burning syndrome is due to immune responses previously described for women in the general community diagnosed with seminal plasma hypersensitivity.

SPECIFIC AIMS: Military and veteran sources will be surveyed to obtain a population of women who developed vaginal burning syndrome after their sexual partners returned from the Persian Gulf.

METHODOLOGY: The population of women with Gulf War vaginal burning syndrome will be compared to our civilian population with seminal plasma hypersensitivity. Relevant seminal plasma proteins will be characterized using immunoaffinity column chromatography, isoelectric focusing, immunoelectrophoresis and SDS-PAGE using seminal plasma from the male sexual partners of experimental and control female groups. Once characterized these proteins will be used for determination of specific immune responses in all groups. Seminal plasma proteins from normal males with and without Gulf War exposure will be exposed to a number of different in vitro chemical conditions (i.e. pyridostigmine, pesticides), vaccines and extreme heat. These proteins will be characterized before and after exposure using functional assays which measure antibody response, complement activation and cellular proliferation. Relevant seminal plasma proteins will undergo amino acid sequencing to determine whether homology with other proteins exist. the effect of an immunosuppressive protein (fraction 1) in humal seminal plasma will also be investigated before and after in vitro exposure to a variety of physical and chemical factors encountered during the gulf war.

EXPECTED PRODUCTS (MILESTONES): If the hypotheses are correct, 1) women with seminal plasma hypersensitivity and vaginal burning syndrome will demonstrate immediate cutaneous reactivity to seminal plasma protein fractions; 2) one or more seminal plasma proteins that cause localized vaginal symptoms in our civilian group of women will also cause similar symptoms in women with Gulf War vaginal burning syndrome; and 3) the ability of seminal plasma proteins to regulate (either stimulate or inhibit) the humoral, cellular or secretory immune responses after exposure to physical and chemical factors encountered in the Gulf War.

STATUS: Study just started (11/96 award)

PUBLICATIONS none to date

Title Physical and Emotional Health of Gulf War Veterans Women

Research Focus: Symptoms/General Health

Research Type: Epidemiology/Clinical Research

Agency DoD

Study Location Ann Arbor, MI

Study Start Date 9/1/96

Estimated Completion Date 8/31/99

Project Status Ongoing

DoD-45

Summary

OVERALL PROJECT OBJECTIVE: This study will compare the prevalence of general and gender specific health problems in 900 Air force women deployed to the gulf and 900 Air force women deployed elsewhere.

SPECIFIC AIMS: To assess whether the prevalence of health problems remain elevated in women deployed to the Gulf at six years post deployment, after controlling for potentially confounding factors such as age, reproductive history, sexual history and lifestyle factors.

METHODOLOGY: This research is to describe the incidence, prevalence, and nature of symptoms associated with Persian Gulf War service within a randomized sample of Air Force women. Our design is developed on previous experience with two studies of Gulf War veteran women as well as the recommendations of numerous military and civilian scientific groups established to address this body of research. Specifically, in previous studies we have used a comparison group of women deployed to sites other than the theater of the war under the assumption they were physically fit for duty and would provide a better comparison than those who did not deploy perhaps for physical health reasons. Further sampling strategies will follow the recommendations for both the National Institutes of Health (NIH, 1994) and the Institute of Medicine (IOM, 1995; Roberts, 1995), who both call for well-designed epidemiologic studies. In both our previous studies we used a randomized stratified factorial design (theater vs. non-theater; parent vs. non-parent, and component (active, guard, and reserve). Similar sampling procedures will be used in this study in order to control for potentially confounding effects of component and parental status. This study will also include detailed information on sexual, reproductive, and menstrual history to allow for more complete analyses of findings.

Sample size and power will detect differences observed in previous studies. Data collection involves recruiting the study participants and maximizing the response rate while minimizing attrition. A single comprehensive questionnaire will provide basic demographic, socioeconomic, and background information and include measures of general physical health and measures of gender-specific health. Mental health measures include assessment of depression, somatization, and 8 PTSD specific to Gulf War service and will include a stressful life event measure. Data processing includes all appropriate range and logic checks. Statistical analyses include descriptive statistics, cross tabulations with chi-square and t-tests, distributions, and multiple regression analyses for health outcomes and deployment status.

EXPECTED PRODUCTS (MILESTONES): Three project years: 1) all planning and pretesting during year 1; one-half of data collection (mail administration) in year 1 and the second half in year 2; all coding and data entry in year 2; and the final report and electronic data file as deliverables.

STATUS: Study has just started year 1 tasks.

PUBLICATIONS none to date

Title Exploratory Data Analysis with the CCEP Database

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency DoD

Study Location Naval Post-Graduate School, Mo

Study Start Date 10/1/95

Estimated Completion Date 9/1/97

Project Status Ongoing

DoD-46

Summary

OVERALL PROJECT OBJECTIVE: To systematically examine the database for interesting relationships, and to find, with a high level of confidence, the most interesting ones without having to do an exhaustive search.

SPECIFIC AIMS: 1) to develop a generic computer package to do exploratory data analysis using genetic algorithms to decide which attributes to consider in the analysis; 2) to apply this package on a number of specific application runs relevant to the Gulf War Syndrome problem; 3) to produce, analyze, and comprehensively document the results of these runs, and produce a set of findings and conclusions.

METHODOLOGY: For the search problem over the space of attributes found in the CCEP database, the main search methodology is based on genetic algorithms. The overall solution methodology consists of exploratory data analysis and knowledge discovery in databases.

EXPECTED PRODUCTS (MILESTONES): 1. The computer software: a) a hypothesis generator module; b) a filtering module; and c) a results presentation and interpretation module.

STATIS/RESULTS TO DATE: Version 1.0 of the Hypothesis Generator Module is complete, tested, and applied in a series of production runs.

PUBLICATIONS none to date

Title Study of Mycoplasmal Infections in Gulf War Veterans

Research Focus: Miscellaneous

Research Type: Epidemiology/Clinical Research

Agency DoD

Study Location Walter Reed Army MC

Study Start Date 10/10/95

Estimated Completion Date 8/30/97

Project Status Ongoing

DoD-47

Summary

OVERALL PROJECT OBJECTIVE: This study is designed to find evidence for mycoplasmal infections in symptomatic Operation Desert Storm veterans, by comparing the rate of seroconversion in symptomatic veterans as compared to healthy Gulf veterans and by culturing for Mycoplasma organisms in symptomatic and healthy Gulf veterans.

SPECIFIC AIMS: See objectives.

METHODOLOGY: This study has two parts: (1) Sera from 200 symptomatic Gulf veterans and 200 healthy Gulf veterans, stored in the U.S. Armed Forces HIV Repository are used. Sera prior to and after deployment to South West Asia are tested for antibody to *M. fermentans*, *M. genitalium*, and *M. penetrans*. (2) Blood, urine, oropharyngeal, and rectal samples in 100 consecutive veterans undergoing evaluation at WRAMC and 100 asymptomatic veterans are tested for evidence of mycoplasmal infection by culture, serology and PCR.

EXPECTED PRODUCTS (MILESTONES): August 1996 - Initial Part One results; March 1997 - Addendum Part One results; August 1997 - Part Two complete.

STATUS/RESULTS TO DATE: Part one of the study was done using 151 cases and 151 age and gender matched controls. There was no statistically significant difference in the seroconversion rate to any of the aforementioned Mycoplasma. However the seroconversion rate was unexpectedly low: 1.5% for controls and 3.0% in cases for *M. fermentans*. The odds ratio (OR) for cases compared to controls was 2.0 with a confidence interval of 0.4 - 10.9. In order to be able to detect an OR of 2 with a background seroconversion rate of 1 - 2% with 80% power, a larger study needs to be done. An addendum to the protocol has been submitted. Part two of the study is still ongoing, and as of 9 Sep 1996, 41 symptomatic veterans and 18 healthy controls have entered the study.

No significant difference in the seroconversion rate to Mycoplasma has been found when comparing symptomatic to healthy Gulf veterans. Because of the low seroconversion rate, the power of part one of the study is low and a larger sample size will allow a better estimation of seroconversion to Mycoplasma in this population.

PUBLICATIONS none to date

Title Assessment of Genomic Instability via Chromosome 7 Inversion Frequency in a Gulf-War Syndrome Cohort vs Selected Control Groups

Research Focus: Immunology

Research Type: Epidemiology/Clinical Research

Agency DoD

Study Location Ft. Detrick

Study Start Date 10/10/95

Estimated Completion Date 5/31/97

Project Status Ongoing

DoD-48

Summary

OVERALL PROJECT OBJECTIVE: This study is designed to determine the frequency of chromosome 7 inversions in blood lymphocytes of four groups of volunteers: (1) symptomatic Gulf War veterans with findings consistent with a diagnosis of autoimmune or collagen vascular disease; (2) Gulf War veterans without abnormalities; (3) symptomatic volunteers with autoimmune or collagen vascular disease; and (4) healthy volunteers with no Gulf War exposure.

SPECIFIC AIMS: See objectives.

METHODOLOGY: Blood will be obtained from twenty five consecutive cases of each of the four groups. The samples are examined for the chromosome 7 inversion blindly in the laboratory of Dr. William Fishbein, an investigator from the AFIP. After the 100 samples the investigators will be unblinded and a statistical analysis will be done.

EXPECTED PRODUCTS (MILESTONES): March 1997 - Collection complete; April 1997 - Analysis complete.

STATUS/RESULTS TO DATE: As of 9 September 1996, a total of 75 volunteers have been enrolled in the study.

No conclusions can be drawn at this time because the groups remains blinded to investigators.

PUBLICATIONS none to date

Title Health Assessment of Persian Gulf War Veterans from Iowa

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency HHS

Study Location CDC and Prevention, Iowa

Study Start Date 12/1/94

Estimated Completion Date 1/31/98

Project Status Ongoing

HHS-1

Summary

OVERALL PROJECT OBJECTIVE: The objective of this study is to assess the prevalence of adverse health outcomes among a random sample of Persian Gulf War veterans who listed Iowa as their home of record. For comparison purposes, this study will also assess the prevalence of adverse health outcomes among a control sample of military personnel who served during the time of the Persian Gulf War, but who were not deployed to the Persian Gulf theater of operations.

SPECIFIC AIMS: This study will address the following specific hypotheses: (1) Persian Gulf War veterans experienced more self-reported health problems in the post-war period than did Persian Gulf-era military personnel who did not serve in the Persian Gulf region; (2) active duty military personnel with service in the Persian Gulf region experienced more self-reported health problems in the post war period than did active duty military personnel who did not serve in the Persian Gulf region; (3) National Guard and reserve personnel with service in the Persian Gulf region experienced more self-reported health problems in the post-war period than did National Guard and reserve personnel who did not serve in the Persian Gulf region; and (4) National Guard and reserve personnel with service in the Persian Gulf region experienced more self-reported health problems than active duty military personnel with comparable service.

METHODOLOGY: Data on self-reported health outcomes are being collected through a telephone survey with a random sample of Persian Gulf War veterans and Persian Gulf War-era controls who listed Iowa as their home of record. Approximately equal sample sizes from four groups of military personnel were selected: (1) exposed (served in Persian Gulf) active duty military personnel; (2) exposed National Guard and reserve personnel; (3) control (Persian Gulf War-era) active duty military personnel; and (4) control National Guard and reserve personnel. Approximately 750 subjects in each group will be interviewed using stratified random sampling with proportional allocation. In addition, each group will be stratified based on branch of military service, pay grade, race, age, and gender.

EXPECTED PRODUCTS (MILESTONES): Expect report of results by early 1997.

STATUS/RESULTS TO DATE: Ongoing; Data collection completed May 1996, initial report submitted for publication in September 1996.

PUBLICATIONS none to date

Title Disease Cluster in a Pennsylvania Air National Guard Unit, EPI-AID 95-18

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency HHS

Study Location CDC, Pennsylvania

Study Start Date 12/1/94

Estimated Completion Date 3/31/95

Project Status Ongoing

HHS-2

Summary

OVERALL PROJECT OBJECTIVE: Evaluate reported cluster of illness in the Pennsylvania 193rd Air National Guard unit.

SPECIFIC AIMS: To characterize patients, determine if there was a cluster, and to identify risk factors for cluster.

METHODOLOGY: Case series survey, cross sectional population survey, and case control study

STATUS/RESULTS TO DATE: EPI - AID is complete. Lab and data analysis continue.

PUBLICATIONS Morbidity and Mortality Weekly Report: Unexplained Illness Among Persian Gulf War Veterans in an Air National Guard Unit, Preliminary Report, August 1990-March 1995. MMWR, 44(23):443-447, 1995.

Title Biomarkers of Susceptibility and Polycyclic Aromatic Hydrocarbon (PAH) Exposure in Urine and blood Cell DNA from U.S. Army Soldiers Exposed to Kuwaiti Oil Well Fires

Research Focus: Environmental
Toxicology

Research Type: Basic Research

Agency HHS

Study Location NIH/NCI/DCE/LCTP/IVP

Study Start Date 1/1/92

Estimated Completion Date 1/31/97

Project Status Ongoing

HHS-3

Summary

OVERALL PROJECT OBJECTIVE: To compare PAH level in soil and air with biomarkers of exposure (urinary metabolites), biologically-effective dose (DNA adducts) and individual susceptibility (genetic polymorphisms) for this group of 62 soldiers. This project is technically not a research project. It was an analysis requested by the U.S. Army Environmental Hygiene Agency, now known as the Center for Health Promotion and Preventive Medicine, as a part of their ongoing exposure assessments.

SPECIFIC AIMS: To determine the extent of exposure and the correlation between these various biomarkers.

METHODOLOGY: Soldiers participating in a USAEHA surveillance project in which ambient PAH monitoring and biomonitoring were performed. Samples of blood and urine were taken in Germany in June (1991), in August, eight weeks after deployment to Kuwait, and in October after the return to Germany. PAH-DNA adducts were measured by benzo[a]pyrene-DNA dissociation-enhanced lanthanide fluoroimmunoassay (DELFI) and aromatic DNA adducts were measured by 32P-postlabeling in blood cell DNA. Urinary benzo[a]pyrene metabolites are being determined by immunaffinity chromatography and fluorescence. Glutathione-s-transferase and cytochrome P450 1A1 polymorphisms have been determined by PCR amplification of the DNA.

EXPECTED PRODUCTS (MILESTONES): The anticipated findings were higher pollution in the area of the soldiers' duty stations and higher levels of DNA adducts and urinary metabolites.

STATUS/RESULTS TO DATE: By both methodologies, blood cell DNA adduct measurements were lower in Kuwait than in Germany in June and October. The increase in adduct levels in October (compared to August in Kuwait) was statistically significant. Urinary metabolite studies are not complete. The data suggest that the location of the soldiers' duty stations in Kuwait represented a cleaner working environment than Germany. Actual PAH measurements of air and soil in Kuwait showed very low levels of contamination. Literature values for ambient PAH measurements for Germany at the same time are much higher.

PUBLICATIONS none to date

Title Suspected Increase of Birth Defects and health Problems Among Children Born to Persian Gulf War Veterans in Mississippi

Research Focus: Reproductive Health

Research Type: Epidemiology Research

Agency CDC

Study Location Jackson

Study Start Date 5/1/94

Estimated Completion Date 2/1/96

Project Status Complete

HHS-4

Summary

OVERALL PROJECT OBJECTIVE: To determine the nature and extent of a reported increase of birth defects and health problems among children born to Persian Gulf War veterans from two units of the Mississippi National Guard. .

SPECIFIC AIMS: To calculate the number and rate of birth defects and health problems in children born to Persian Gulf War veterans from two units of the MS National Guard after their return from overseas service, and determine whether an excess of birth defects/health problems occurred.

METHODOLOGY: Descriptive survey by medical record review, supplemented by parent/physician interview as required. Comparison of observed numbers/rates with expected numbers/rates from birth defect surveillance systems, epidemiological studies, etc.

EXPECTED PRODUCTS (MILESTONES): Final report published by CDC on 12/19/94 (Field Epidemiology Report #95-01).

STATUS/RESULTS TO DATE: The total number of all types of birth defects was not greater than expected. The frequency of premature birth, low birth weight, and other health problems appeared similar to that in the general population.

PUBLICATIONS Penman AD, Tarver RS. No evidence of increase in birth defects and health problems among children born to Persian Gulf War veterans in Mississippi. Military Medicine, 161(1):1-5, 1996.

Title Mortality Follow-up Study of Persian Gulf Veterans

Research Focus: Mortality

Research Type: Epidemiology Research

Agency VA

Study Location VACO

Study Start Date 7/1/94

Estimated Completion Date 7/1/3196

Project Status Complete

VA-1

Summary

OVERALL PROJECT OBJECTIVE: VA's Environmental Epidemiology Service is undertaking a retrospective Follow-up Mortality Study of Persian Gulf Veterans that will compare the overall mortality rates and cause-specific mortality rate of all 697,000 servicemembers who served in the Persian Gulf theater of operations anytime between August 1990 and May 1991 with those of a comparison group of 803,526 service members randomly selected from various subsets of all servicemembers who were in service anytime between August 1990 and May 1991 but who were not deployed to the Persian Gulf theater.

SPECIFIC AIMS: Are there excess deaths among Persian Gulf veterans from various natural and external causes in comparison to their non-Persian Gulf Veteran counterparts?

METHODOLOGY: A retrospective cohort mortality study; 697,000 study subjects, 800,000 controls; Cox regression model, SMR analysis. Vital status has been determined using a VA database known as the Beneficiary Identification and Record Locator Subsystem (BIRLS) and a Social Security Administration file for deaths reported through 1993. Death certificates have been requested from VA regional offices, Federal Records Centers or from state vital statistics offices. Cause of death are coded by a qualified nosologist using the International Classification of Diseases, 9th revision, without the knowledge of whether the decedent served in the Persian Gulf area.

As the first mortality follow-up of Persian Gulf veterans, this study represents an important first step in addressing the health concerns of Persian Gulf veterans. The study results as reflected in mortality should provide an early warning for any possible life threatening health conditions as a consequence of Persian Gulf service. The study will be periodically updated to ascertain any long-term consequences of Persian Gulf service on mortality outcomes.

EXPECTED PROEJCTS (MILESTONES): Data collection is complete. Preliminary results were presented at the American Public Health Association Meeting in San Diego CA October, 1995. A final report was submitted in April 1996 to a scientific journal for publication.

STATUS/RESULTS TO DATE: Preliminary analysis indicates that the overall mortality rate is higher in Persian Gulf veterans compared to non-deployed era veterans. However, when causes due to accident, suicide and homicide are accounted for, there is no difference in mortality rate between the two groups.

PUBLICATIONS Manuscript accepted for publication.

Title National Health Survey of Persian Gulf Veterans

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency VA;

Study Location VACO

Study Start Date 7/1/94

Estimated Completion Date 6/30/98

Project Status Ongoing

VA-2

Summary

OVERALL PROJECT OBJECTIVE: To estimate prevalence of various symptoms and other health outcomes for Persian Gulf War veterans.

SPECIFIC AIMS: To estimate and compare prevalence of various symptoms, medical conditions, and unexplained illnesses in Persian Gulf war veterans and those of non-Persian Gulf veterans.

METHODOLOGY: A population-based health survey. Several studies are currently underway that investigate the incidence, prevalence, and nature of illnesses in Gulf War veterans. The National Health Survey of Persian Gulf Veterans and Their Family Members is conducted in three phases. In Phase I, a questionnaire was mailed to each of 30,000 veterans (15,000 Persian Gulf Veterans; 15,000 non-Persian Gulf Veterans). Multiple follow-up mailings were made to increase the response rate. In Phase II, a sample of 8,000 non-respondents will be randomly selected and a telephone interview will be attempted using a CATI questionnaire which includes a question on reasons for refusal. Telephone interviews with the non-respondents will assist in assessing potential non-respondent bias and will supplement the postal survey data. In addition, during Phase II, selected self-reported data collected by the postal questionnaire will be validated through records review for 2,000 veterans from each group. In Phase III, the same 2,000 veteran respondents and their family members from each group will be invited to participate in a comprehensive physical examination under a uniform comprehensive clinical examination protocol at a VA, DoD, or private medical facility.

The scope of the survey spans 3 years: Phase I was completed at the end of the first year (June 1996); Phase II by October 1997; and Phase III by the end of the third year (June 1998).

EXPECTED PROJECTS (MILESTONES): Publication in a peer-reviewed journal.

STATUS/RESULTS TO DATE: The proposed study protocol and questionnaire were peer-reviewed and approved by an external scientific oversight committee in April 1995. The proposed survey questionnaire was approved by the Office of Management and Budget (OMB) in September 1995. The initial questionnaires were mailed in November 1995 and the first supplemental questionnaires were mailed in January 1996 to 20,426 non-respondents and individuals with new mailing addresses. Phase I of the survey was completed in June 1996.

PUBLICATIONS none to date

Title Use of Roster of Veterans Who Served in Persian Gulf Area

Research Focus: Miscellaneous

Research Type: Epidemiology Research

Agency VA/DoD

Study Location VACO

Study Start Date 7/1/94

Estimated Completion Date 7/31/96

Project Status Ongoing

VA-3

Summary

OVERALL PROJECT OBJECTIVE: To properly address the issue of possible exposure to environmental hazards, all individuals who served in the Persian Gulf region need to be identified.

SPECIFIC AIMS: To prepare a computer file of over 697,000 troops assigned to the Persian Gulf area during Operation Desert Shield/Desert Storm.

METHODOLOGY: The U.S. Army and Joint Services Environmental Support Group (ESG) is in the process of computerizing troop unit locations in the Persian Gulf Theater.

EXPECTED OUTCOMES (MILESTONES): Complete description of unit locations in the Persian Gulf Theater.

STATUS/RESULTS TO DATE: The personnel database is now operational (about 700,000 individuals). Troop movement software is now operational. Documenting troop movements from Combat Records is continuing and is over 90% complete, based on the records currently identified. This database has been made available to VA's Environmental Epidemiology Service (EES), giving VA access to demographic data on all troops stationed in the Persian Gulf. The risk assessment data are obtained, and oil field emissions modeling data are synthesized. Initial results of unit-level values are expected in May of 1996.

RESULTS: Troop roster and troop unit locations were available as of the end of July 1996.

PUBLICATIONS none to date

Title Evaluation of Cognitive Functioning of Persian Gulf Veterans**Research Focus:** Brain & Nervous System**Research Type:** Clinical Epidemiology Research**Agency** VA**Study Location** VAMC Boston**Study Start Date** 10/1/94**Estimated Completion Date** 9/30/99**Project Status** Ongoing

VA-4A

Summary

OVERALL PROJECT OBJECTIVE: The primary focus of this research project is to determine whether specific cognitive deficits or deficit patterns are associated with the presence of self-reported health complaints and/or with hazardous environmental exposures in the Gulf. (Exposure information will be obtained either from self-report, exposure modeling, and DoD data on troop locations). In examining these associations, the influence of war-zone stress, PTSD symptomatology, psychological distress, and post-deployment life stressors is being evaluated.

SPECIFIC AIMS: The specific objectives of this study are: (1) to observe and determine whether cognitive performance deficits are associated with self-reported health complaints stemming from Persian Gulf deployment; (2) to determine the relationship of environmental exposure (self-report and based on an independent exposure protocol) during deployment to cognitive performance; (3) to characterize subsets of cognitive patterns or deficits among exposure classes; (4) to delineate the association of cognitive alterations or deficits with levels of combat exposure, combat stress, and PTSD symptomatology; and (5) to conduct a preliminary examination of the relationship among health symptoms, hazardous environmental exposure, and other war-zone experiences, specifically traumatic war-time stressors and ensuing trauma symptomatology (Sutker, Uddo, Brailey, & Allain, 1993; Wolfe, Keane, & Young, in press). Identification of diagnostic predictors and their relationship to outcomes of interest will help establish preliminary models related to important components of the military experience. The development of these models will aid Department of Veterans Affairs (VA) and Department of Defense (DoD) activities related to veterans' health care by: (1) facilitating symptom recognition and diagnosis in areas of growing concern (environmental exposure and traumatic stress following war), (2) emphasizing interdisciplinary approaches, (3) contributing to treatment planning, and (4) providing a baseline against which cognitive and mental status change over time can be gauged. Observations and findings from this study can lead to more focused investigation of cognitive functions that may be directly associated with defined exposures and/or PTSD symptomatology.

METHODOLOGY: Subjects in this face-to-face study are contacted by phone and asked to participate in as many parts of the protocol as they would like. The protocol consists of an in-depth questionnaire which asks about background information relating to job, education, family history, medical and psychological problems, an interview with an Environmental Health specialist about experiences and exposures while in the Gulf, a psychological interview with a clinical psychologist asking about readjustment issues and psychiatric stress since the war, and neuropsychological tests examining primarily memory, attention, and learning abilities.

EXPECTED PRODUCTS (MILESTONES): Multiple scientific manuscripts, annual reports, annual reports of Boston Environmental Hazards Center, longitudinal data on stress and health.

STATUS/RESULTS TO DATE: This study constitutes Time 3 of the Desert Storm Reunion Survey. The Ft. Devens ODS Reunion Survey represents a longitudinal assessment of readjustment of Persian Gulf War veterans returning through Ft. Devens, Massachusetts, following their return from the Persian Gulf region.

To date, 220 subjects from the Devens cohort sample have been tested (137 have come to the Boston VAMC and completed all parts of the protocol; 83 have partially completed the protocol generally because they live geographically too far away). In addition, 47 veteran subjects (part of the larger Devens cohort but not the projected sample), and 50 controls (veterans deployed to Germany but not the Gulf) have completed the Project #1 protocol).

In order to substantiate and corroborate information reported to us by veterans regarding where they were located and potential hazardous exposures in the Gulf, we are proceeding with obtaining computerized database information on exogenous exposure, potentially using grid coordinates linked to modeling data from DoD. We have received information on unit locations during the Gulf War from the U.S. Army and Joint Services Environmental Support Group. Unit location information is being compiled and plans for analysis are being discussed.

In Year 3, we will conclude data collection and conduct data analyses, with manuscript preparation to follow.

- PUBLICATIONS** Proctor S, Wolfe J, Friedman M. Evaluation of health symptoms reported by Gulf War veterans. Paper presented at the Annual Meeting (9/94) of the International Society for Environmental Epidemiology, Research Triangle Park, North Carolina.
- Wolfe J, Brown PJ, Bucsela ML. (1992) Symptom responses of female Vietnam veterans to Operation Desert Storm. *Am J Psychiatry*, 149, 676-679.
- Wolfe J, Brown P, Kelley J. (1993) Reassessing war stress: exposure and the Gulf War. *J Soc Issues*, 49, 15-31.

Title Evaluation of Neurological Functioning in Persian Gulf Veterans

Research Focus: Brain & Nervous System

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC Boston

Study Start Date 10/1/94

Estimated Completion Date 9/30/99

Project Status Ongoing

VA-4B

Summary

OVERALL PROJECT OBJECTIVE: This study evaluates neurological functioning in returning Persian Gulf war veterans who present with nervous system signs and symptoms of the type described as "Gulf War Syndrome". This study uses sophisticated clinical neurophysiological techniques capable of detecting subtle changes in peripheral and central nervous system functioning: electroencephalography (EEG); evoked potential (EPs); nerve conduction studies (NCV) and functional magnetic resonance imaging (MRI).

SPECIFIC AIMS: The specific objectives of this study are: (1) to objectively describe Persian Gulf War veterans' neurological status using standard clinical methodology, (2) define to observe and determine patterns of central and/or peripheral nervous system deficits in the four designated diagnostic groups compared to controls, and (3) to explore whether similar patterns of particular exposure characteristics exist within the diagnostic groups and whether distinct patterns exist between the groups.

METHODOLOGY: Subjects are veterans from the subjects evaluated in Project 1 who have been diagnosed with disorders which have an hypothesized environmental trigger and include neurological complaints (presumed neurotoxicant encephalopathy, multiple chemical sensitivity, chronic fatigue syndrome and post-traumatic stress disorder). Approximately 300 subjects (200 selected cases and 100 controls) will be selected from Project #1 and examined over a five year period. Approximately 10 persons from each of the four diagnostic categories and 20 control subjects will be enrolled for study each year. These subjects will have a neurologic examination and questionnaire, EEG, EPs, and MR. Those subjects with presumed neurotoxicant encephalopathy and those serving as controls also will have nerve conduction studies.

Since all subjects recruited for study are from subjects studied in Project 1, the groups are similar in age and gender distribution. Thus, subjects are not directly matched by gender and age with controls, but attention to these demographic factors will be made in selecting appropriate controls.

EXPECTED PRODUCTS (MILESTONES): In this study, we expect to determine if there are differences in subtle neurological functioning between veterans diagnosed with environmental health-related diagnoses of organic brain syndromes resulting from toxicant exposures, PTSD, MCS, or CFS compared to controls.

STATUS/RESULTS TO DATE: Electrophysiological testing of a cohort of PGW veterans is currently underway (n=50 clinical PGW patients). Our current plan is for the focus of the project to be on SPECT and MRI protocols, along with the nerve conduction study. Methodology and pilot studies to test the imaging methodology are currently in progress.

In light of recent DoD reports of sarin detection in the Gulf region during the war, we are considering the development of an appropriate evoked potential (EP) study protocol.

PUBLICATIONS none to date

Title Gulf War And Vietnam Veterans Cancer Incidence Surveillance

Research Focus: Miscellaneous

Research Type: Epidemiology Research

Agency VA

Study Location VAMC Boston

Study Start Date 10/1/94

Estimated Completion Date 9/30/99

Project Status Ongoing

VA-4C

Summary

OVERALL PROJECT OBJECTIVE: To examine the pattern of cancer diagnosed in Massachusetts Vietnam veterans as compared with Vietnam-era veterans for the time period 1988-1993. This linkage will be accomplished by linking a computer tape of Massachusetts veterans who received differential bonuses to the Massachusetts Cancer Registry master file and analyzing the resulting linked cases, as was done for the years 1982-1988 in prior study by the Principal Investigator.

Another objective is to establish a database linkage for New England area Persian Gulf War veterans so as to be able to examine cancer incidence in this cohort at a later point in time.

SPECIFIC AIMS: 1. Monitor cancer incidence in Gulf War and Vietnam veterans of New England states, as part of the overall surveillance of disease in veterans exposed to environmental hazards; 2. Extend previous studies of cancer incidence and mortality by collecting and analyzing data on Massachusetts Vietnam veterans diagnosed in the years 1988-1993; 3. Analyze the results of the Massachusetts veterans cancer incidence linkage in a nested case-control design incorporating information on military and civilian occupations, branch of service and, where possible, location of service; 4. Establish a roster of Gulf War veterans in New England states, with identifying information such as names, dates of birth, and social security numbers, resulting in a computer file of Gulf War veterans that can be used in future linkage studies examining cancer incidence and mortality from various diseases; 5. Provide a database from which to plan additional clinical and preventative interventions to reduce morbidity and mortality from targeted diseases.

METHODOLOGY: In Year 1, we planned to initiate the linkage. In years 2-5, we plan to sort the cases into cancers of interest and other (auxiliary) cancers, analyze the data as a "nested" case-control study, and present odds ratios for specific cancers in Vietnam veterans compared with Vietnam-era veterans. Also in years 2-5, we plan to devise a system for linking the roster of Gulf War veterans in the New England states with cancer registries in all states which have population-based data.

EXPECTED PRODUCTS (MILESTONES): In this study we expect to determine cancer incidence rates in Massachusetts Vietnam veterans for the period 1988-1993. At completion of year 2 of the study, we expect to have preliminary results based on analysis of this database. Results pertaining to cancer incidence in Gulf War veterans is not expected for 10 years or so due to the latency period in cancer development.

STATUS/RESULTS TO DATE: The linkage program has been re-written and initial linkages run. Preliminary results have been obtained for the Massachusetts veterans bonus tapes linkage to the Massachusetts Cancer Registry. The mechanics for the linkages to the other New England Central Cancer Registries is in progress.

PUBLICATIONS none to date

Title Evaluation of Respiratory Dysfunction Among Gulf War Veterans

Research Focus: Environmental
Toxicology

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC Boston

Study Start Date 10/1/94

Estimated Completion Date 9/30/96

Project Status Ongoing

VA-4D

Summary

OVERALL PROJECT OBJECTIVE: To assess respiratory status in relation to exposure to oil fire pollution in Gulf War veterans and evaluate the relationship between measures of pulmonary dysfunction and respiratory symptoms and exposure in subjects recruited for Project #1.

SPECIFIC AIMS: 1. Create a cumulative personal exposure estimate for each subject utilizing the U.S. Army Environmental Hygiene Agency exposure assessment data for their unit combined with geographic specific information which maps each unit's location in the Persian Gulf War theater; 2. Assess respiratory status using standardized respiratory questionnaire; 3. Assess respiratory function with physical examination and pulmonary function testing; 4. Assess pre-existing asthma risk with total serum IgE levels; 5. Assess non-specific bronchial responsiveness (BHR) as a measure of early outcome and as a potential risk factor in the development of lung disease by using methacholine challenge testing (initiating in Year 2 of the study); 6. Examine possible predictors of respiratory function (PFT's and methacholine challenge test) using cumulative environmental exposure assessment variable, respiratory medical history, occupational history, and smoking status variables; 7. Develop a database from which to plan preventative interventions to reduce morbidity and mortality from respiratory diseases.

METHODOLOGY: Subjects will be veterans from the subjects evaluated in Project 1. Each will complete a standardized respiratory questionnaire, systematic cardio-pulmonary physical exam, and pulmonary function testing. Spirometric measures will include forced expiratory volume in one second (FEV1), forced vital capacity (FVC) and FEV1/FVC in accordance with American Thoracic Society recommendations. Subject data will be adjusted for age, height and gender and transformed to percentage predicted values using Knudson predictive equations. Blood will be drawn by venapuncture at the time of the visit and total serum IgE, complete blood count and differential and quantitative immunoglobulin levels will be measured. Additional blood samples will be drawn and stored for future laboratory tests (e.g., DNA analyses, infectious diseases). Bronchial responsiveness will be determined via methacholine challenge testing starting in Year 2. Nonspecific bronchial hyperresponsiveness has been suggested as a risk factor for, or an early event in the development of both acute and chronic occupational lung diseases. Occupational exposures to irritant substances at concentrations similar to the Gulf War exposures have been shown to cause airway hyperresponsiveness and it is believed that these exposures might be associated with the development of asthma.

EXPECTED PRODUCTS (MILESTONES): In this study, we expect to determine if there are differences in respiratory function (PFTs) in Gulf War veterans associated with cumulative personal exposure estimates obtained from exposure modeling by the U.S. Army Hygiene Agency. At the completion of Year 3 of the study, we expect to have preliminary results based on analyses of the data collected at that time.

STATUS/RESULTS TO DATE: To date, a total of 75 subjects have been recruited for the study. Blood samples are being collected and pulmonary function testing performed according to schedule. Methodology for methacholine challenge testing will be piloted and integrated into the existing study protocol in the fall of 1996.

PUBLICATIONS none to date

Title The Aromatic Hydrocarbon Receptor (AhR) as a Biomarker of Susceptibility

Research Focus: Environmental
Toxicology

Research Type: Basic Research

Agency VA

Study Location VAMC Boston

Study Start Date 10/1/94

Estimated Completion Date 9/30/99

Project Status Ongoing

VA-4E

Summary

OVERALL PROJECT OBJECTIVE: The objective of this project is to test the hypothesis that the aromatic hydrocarbon receptor (AhR) is a molecular biomarker for polycyclic aromatic hydrocarbon (PAH) susceptibility. Veterans of the Persian Gulf war were potentially exposed to relatively high doses of PAHs in smoke emanating from Kuwaiti oil well fires. The high incidence of physical complaints by Gulf War veterans may reflect previously documented PAH toxicities including suppression of the immune system and neurologic dysfunction.

SPECIFIC AIMS: 1. Confirm that AhR expression levels correlate with PAH bioactivity; 2. Optimize the use of single strand conformational polymorphism (SSCP) analysis to detect AhR gene polymorphism and mutations in mice; 3. Apply results to human studies. Results obtained in the fulfillment of aims #1 and 2 will define the conditions for employing AhR levels and gene polymorphism as molecular biomarkers of PAH susceptibility.

METHODOLOGY: The first aim of the project is to confirm that the level of AhR in mice correlates with PAH toxicity and carcinogenicity. To do this first we propose genetically engineering AhR transgenic mice in which elevated AhR expression is directed to lymphocytes and then assessing a) PAH-induced immunosuppression as a representative indicator of organ toxicity and b) lymphocyte and lung transformation as measures of cancer risk in AhR transgenic mice. To prepare for human studies, we will evaluate AhR polymorphism in mice using single strand conformational polymorphism (SSCP) analysis. Double stranded DNA from samples of veterans' blood is separated by heating followed by rapid cooling on ice. The three-dimensional conformation reassumed by each strand is determined by its nucleic acid sequence. Single nucleotide changes can be detected when the reannealed DNA is run on 6% acrylamide gels.

To apply results to humans, polyclonal and monoclonal antibodies to human AhR (and/or ARNT) will be produced and employed in conventional or PCR-based ELISAs of AhR protein levels in peripheral blood lymphocytes from Persian Gulf War veterans who complete Projects #1 and 4. **EXPECTED PRODUCTS (MILESTONES):** This project will result in the production of new strains of mice which differ in their responsiveness to environmental pollutants. These mice will represent invaluable tools in investigating the effects of these pollutants in humans. We will also develop the technology to screen veterans of the Persian Gulf war for genetic factors which could put them at risk for immune defects and cancer.

STATUS/RESULTS TO DATE: As part of the first aim of this project we have successfully generated 8 chimeric mice, i.e., mice derived from both the normal cells of the blastocyst and from the blastocyst-injected embryonic stem cells. We are currently testing the ability of these stem cells to introduce the gene mutation into the germ line of these chimeric mice by breeding the chimeric mice with normal mice and looking for the transmission of the AhR mutation in the first generation. Germ line transmission of a mutated or overexpressed AhR transgene is essential to our studies. It is necessary to set up biologic assays to assess the effects of overexpressing the AhR gene in mutant mice. To this end we are setting up assays of immune responses in vivo (plaque forming cell assays, ELISA spot assays) and in vitro (Mishell/Dutton cultures). Antigens for these studies are being made and reagents required for the assays have been collected. (A microplate reader has been purchased and is being interfaced with a PC for rapid analysis of ELISA results.)

In order to quantitate the expression of AhR in mutant or in normal mice by western blotting and by novel ELISA techniques in aim #1, it is necessary to produce AhR-specific monoclonal antibodies. To this end we have expressed a full length AhR protein in a bacterial expression system, have

purified about 100 mcg of protein, and are preparing to immunize rats with the protein. In the meantime, we have developed an AhR ELISA assay with which to screen rat sera and putative hybridomas derived from immunized rats for anti-AhR antibodies.

In the proposal we have entertained the possibility that additional factors, e.g., ARNT accessory molecules, limit AhR activity. To prepare for this possibility, we have obtained anti-ARNT antibodies from a collaborator for western blotting analysis and have subcloned the murine ARNT gene for expression in bacterial systems. Purified ARNT will be used to generate monoclonal anti-ARNT antibodies as described for AhR. We have also set up collaborations to employ in situ hybridization and ligand binding assays to evaluate levels of AhR expression and function in transgenic mice. In addition, we have been looking for genetic polymorphisms in the human AhR gene. After segmenting the gene into a ligand binding site and a DNA binding site and examining it using Sequence Specific Conformational Polymorphism techniques, we have found two alleles at each site, based on about 40 samples from the Center's veteran population (Project 4 subjects).

PUBLICATIONS none to date

Title Validity of Computerized Tests**Research Focus:** Brain & Nervous System**Research Type:** Clinical Research**Agency** VA**Study Location** VAMC Boston**Study Start Date** 10/1/94**Estimated Completion Date** 9/30/99**Project Status** Ongoing

VA-4F

Summary

OVERALL PROJECT OBJECTIVE: The objective of this project is to continue the validation process of the Neurobehavioral Evaluation System (NES), a battery of computer-assisted behavioral tests developed for the purpose of detecting brain dysfunction secondary to exposure to neurotoxicants, with an expanded battery of subtests. The NES tests are derived from standard neuropsychological tests that have been well characterized in terms of brain-behavior relationships, but they differ in input and output modality and in other respects from traditional tests. Therefore, the validity of the NES subtests can only be verified by testing patients with known brain damage and showing that such damage affects performance on those tests. The sensitivity of the NES to neurotoxicant exposure cannot be fully interpreted, in terms of CNS mechanisms, without such validation.

SPECIFIC AIMS: 1. Assess the validity of the expanded battery of NES tests within the patient groups (Parkinson's Disease, Multiple Sclerosis, focal lesion patients) studied in the previous phase of this research. 2. Expand the validation study to include patients with other neurologic (Alzheimer's Disease, Huntington's Disease) and psychological disorders (PTSD), as well as those with conditions potentially induced by hazardous environmental or occupational exposure (MCS, CFS). 3. Correlate performance on the new NES subtests with performance on the standard paper-and-pencil tests on which they are based. 4. Determine the sensitivity of the NES subtests to the progression of neurologic disease by longitudinal testing of subject groups with deteriorating disorders.

METHODOLOGY: Neurologic subjects are being recruited from both the Boston VAMC and Boston University Medical Center. Subjects in the MCS, CFS and PTSD groups will be recruited from the population of Gulf War veterans assessed and diagnosed with these disorders in Project #1. PTSD diagnoses will be reviewed by Dr. Wolfe; MCS cases are being identified using criteria specified by Cullen (1987) and CFS cases are being identified using criteria specified by Fukuda et al., 1994. Each subject will have an initial interview to provide demographic data followed by administration of the Mini-Mental Status Examination and WAIS-R Information and Picture Completion subtests (40 minutes). Subjects meeting inclusion criteria will then be administered the expanded NES battery (approximately 100 minutes).

EXPECTED PRODUCTS (MILESTONES): This study has important clinical and research implications: (1) to facilitate the assessment of patients with suspected subtle brain damage secondary to exposure from neurotoxicants or from other diagnoses with a hypothesized environmental trigger (MCS, CFS, PTSD) by providing a sensitive, relatively brief battery of tests of CNS function that can be easily administered; (2) to provide a test battery for which brain-behavior relationships are known (providing measures which will then be useful in hypothesis-driven research on the cerebral localization of neurotoxicant effects); (3) to provide tests with known diagnostic validity for application to clinical situations. We expect to have preliminary results based on analyses of the data collected in the first years of the study, but the total project won't be complete for 3 more years.

STATUS/RESULTS TO DATE: Data analysis and manuscript writing have proceeded in Year 1 describing the validity of NES2 in various patient groups. The NES3 battery has been developed and is now being piloted.

PUBLICATIONS Kregel M, White RF, Diamond R, Letz R, Cyrus P, Durso R. A comparison of NES2 and traditional neuropsychological tests in a neurologic patient sample.

Neurotoxicology and Teratology 1996; 18:435-439.

White RF, Diamond R, Krengel M, Lindem K, Feldman RG: Validation of the NES2 in Patients with Neurologic Disorders. Neurotoxicology and Teratology 1996; 18: 441-448.

Title Health and Exposure Survey of Persian Gulf Veterans

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency VA

Study Location VAMC East Orange

Study Start Date 10/1/94

Estimated Completion Date 9/30/96

Project Status Ongoing

VA-5A

Summary

OVERALL PROJECT OBJECTIVE: To survey 2800 Persian Gulf War veterans randomly sampled from the Northeast quadrant of the U.S. to determine risk factors and their relationships to symptom clusters that could represent significant health problems for Gulf veterans.

SPECIFIC AIMS: 1. To provide health and medical histories of veterans who served in the Persian Gulf and veterans from the same period who were not deployed to the Gulf; 2. To characterize the medical and combat experiences of these veterans during the Gulf war; 3. To perform case control comparisons for various categories and combinations of symptoms with respect to individual and environmental risk factors identified in Aims 1 and 2.

METHODOLOGY: The survey will be mailed from Environmental Epidemiol Service to veterans who served in the Gulf and those in the services at the time of the war but who remained stateside. This survey will be mailed to 2800 veterans on the Persian Gulf Registry. This survey will include a symptom checklist, an environmental risk factor survey, a family and social support survey, and anxiety and depression scales. Multivariate analysis of the resulting information will include cluster analysis, principal components factor analysis, and multidimensional scaling. From these analyses we expect to be able to develop one or more case definitions for the unexplained illnesses afflicting Persian Gulf veterans.

EXPECTED PRODUCTS (MILESTONES): We expect a high prevalence of Chronic Fatigue and Chemical Sensitivity in veterans with unexplained illness. We also expect to delineate a series of risk factors for the development of these illnesses, and for Post-traumatic Stress Disorder which may cluster with one or both of these illnesses. We expect these results to be available by the summer of 1996.

STATUS/RESULTS TO DATE: Data collection is almost complete. We have received 1,400 (57%) of our questionnaires back, and will close data collection on September 1, 1996 with a target of 60%. Symptom data has been preliminarily analyzed. At this point, 18% of the purposive sample returns meet 1988 criteria for CFS, 31% meet 1994 criteria for CFS, and 11% meet MCS case criteria. The mean number of endorsed symptoms out of 48 total was 24, with headaches, difficulty remembering, and fatigue being the most bothersome. Final analyses, incorporating risk factors, should be complete by January 1997.

PUBLICATIONS none to date

Title Physiological and Psychological Assessments of Persian Gulf Veterans

Research Focus: Immunology

Research Type: Clinical Research

Agency VA

Study Location VAMC East Orange

Study Start Date 10/1/94

Estimated Completion Date 3/1/97

Project Status Ongoing

VA-5B

Summary

OVERALL PROJECT OBJECTIVE: This project will determine if some of the unexplained medical illnesses in Persian Gulf veterans may be similar to Chronic Fatigue Syndrome or Chemical Sensitivity in civilian populations. It will include viral/immunological studies, neuropsychological studies, and studies of physiological responses to a number of physical and cognitive challenges. A series of psychosocial factors will be evaluated to determine whether they are risk factors for the illnesses suffered by these veterans. Because female veterans are overrepresented on the Persian Gulf registry in proportion to the number that served in the Gulf, we expect female veterans to make up half of our study subjects.

SPECIFIC AIMS: 1. To determine whether viral or cytokine patterns may suggest an infectious agent as a cause of illness in Persian Gulf veterans; 2. To determine if these veterans suffer chronic fatigue or chemical sensitivity; 3. To determine psychosocial risk factors that might have predisposed some veterans to develop their medical problems; 4. To determine if there are neuropsychological deficits in Persian Gulf veterans; 5. To determine if these veterans have abnormal physiological responses to physiological and cognitive challenges.

METHODOLOGY: Persian Gulf veterans that have chronic fatigue, chemical sensitivity, or a combination of these, and control era veterans not deployed to the Gulf will be recruited for these studies. Blood samples will be drawn, peripheral lymphocytes will be isolated, and polymerase chain reaction will be used to quantify herpes, epstein-barr and other viruses and to assess the level of interleukins and TNF- α . The subjects (80/group) will fill out a series of psychosocial instruments and environmental exposure surveys. A battery of neuropsychological tests will be given in conjunction with an MRI. Finally, a series of challenges will be given including a tilt test, hand grip test, mild exercise on a stationary bicycle, and a cognitive stressor. Blood pressure, heart rate, cardiac output, expired CO₂, and skeletal muscle blood flow will be assessed during and after these tests.

EXPECTED PRODUCTS (MILESTONES): We expect a number of the unexplained illnesses in Persian Gulf veterans will be similar to chronic fatigue syndrome and multiple chemical sensitivity. Our studies on civilians with chronic fatigue suggest that interleukins 6 and 7 and some of the herpes viruses might be elevated. We have also seen neuropsychological deficits in memory tasks and some decrease in white matter in the MRIs. Finally, we expect abnormal responsiveness to some of the physiological stimuli, but it remains unclear whether there will be hyper- or hyporesponsiveness.

STATUS/RESULTS TO DATE: Persian Gulf veterans seen here at the East Orange VA Medical Center were mailed a screening form to evaluate their suitability for entry into studies of chronic fatigue and chemical sensitivity. Additional veterans from an epidemiological survey of 2,600 Persian Gulf veterans in the northeast United States are now also being screened for entry into the studies in this project. To date, 48 subjects have been enrolled in our studies. (Based on screen form responses, 17 met criteria for CFS, 6 for MCS, 7 for both CFS and MCS, and 16 for healthy controls.) All studies on these veterans are progressing, but sufficient numbers for statistical analysis are not expected until the end of 1996. Final results from this project will be available in the summer of 1997.

PUBLICATIONS none to date

Title Effects of Exertion and Chemical Stress on Persian Gulf Veterans**Research Focus:** Immunology**Research Type:** Clinical Research**Agency** VA**Study Location** VAMC East Orange**Study Start Date** 4/1/97**Estimated Completion Date** 9/30/99**Project Status** Ongoing

VA-5C

Summary

OVERALL PROJECT OBJECTIVE: This project will examine several hypotheses about the chronic fatigue and chemical sensitivity that may account for some of the unexplained illnesses in Persian Gulf veterans. Specifically, it will examine the maximum exercise capacity of these veterans compared to similar era veterans who were not deployed to the gulf. Following this, the physiological, immunological, and endocrine responses to a submaximal exercise test will be assessed. In another series of studies, double-blind controlled exposures to a chemical challenge will determine whether specific medical complaints, physiological responses, and cognitive impairments can be measured in chemically sensitive veterans. Because female veterans are overrepresented on the Persian Gulf registry in proportion to the number that served in the Gulf, we expect female veterans to make up half of our study subjects.

SPECIFIC AIMS: 1. To determine whether maximal exercise capacity is compromised in Persian Gulf veterans with chronic fatigue, chemical sensitivity, or a combination of these illnesses.

2. To determine whether the physiological, immunological, or neuroendocrine responses to a submaximal exercise are different in these veterans.

3. To determine whether object medical symptoms, immune responses, physiological responses, or cognitive impairments can be measured during double-blind exposures to a chemical challenge.

METHODOLOGY: The veterans with chronic fatigue, chemical sensitivity or both, as well a control era veterans who were not deployed to the Gulf (30/group), will be given a standard maximal exercise test on a treadmill and VO₂max will be determined. Then, they will be given a submaximal exercise challenge at a relative work load during and after which blood sample will be drawn to assess cytokine responses, glucose and lactate responses, and adrenal stress hormone responses. The chemical challenges will be performed in the exposure chamber at the Environmental and Occupational Health Sciences Institute in Piscataway NJ. In order to perform double-blind exposures, the subjects will be given dermal exposures of phenylethyl alcohol (PEA), which is absorbed through the skin, in a situation where they cannot smell it. They will also receive a comparable inhalation dose to PEA. Autonomic arousal (blood pressure, heart rate), cognitive performance, nasal resistance, and markers of nasal inflammation will be measure before, during, and after exposure to PEA.

EXPECTED PRODUCTS (MILESTONES): In our civilian chronic fatigue patients, VO₂max is slightly but significantly lower than sedentary controls, and we expect the same in Persian Gulf veterans with fatigue. We expect some abnormal responses to the submaximal exercise, but we are only now completing those studies in our civilian patients with fatigue. We also expect that veterans with chemical sensitivity will have greater responses to the chemical exposure than those that are not chemically sensitive.

STATUS/RESULTS TO DATE: Subjects are being recruited and evaluated through Project 2. Equipment for psychophysiologic monitoring has been purchased and installed. Pilot data for the neurobehavioral test and piloting of the psychophysiologic protocol is being collected. These are the last studies in the Environmental Hazards Research Center at the East Orange DVA Medical Center and are not planned to begin until 1997. There are no results to date.

PUBLICATIONS none to date

Title Effects of Genetics and Stress on Responses to Environmental Toxins

Research Focus: Pyridostigmine Bromide

Research Type: Basic Research

Agency VA

Study Location VAMC East Orange

Study Start Date 10/1/94

Estimated Completion Date 9/30/97

Project Status Ongoing

VA-5D

Summary

OVERALL PROJECT OBJECTIVE: This project will determine whether genetic susceptibility to stress and exposure to chronic stress will result in persistent sensitization to potentially toxic effects of pyridostigmine bromide and aromatic hydrocarbons. In addition, it will examine the behavioral consequences of chronic exposure to these toxins.

SPECIFIC AIMS: 1. To expose WKY (stress-hyperresponsive) and SD (control) rats to chronic stress and then study the sensitivity to pyridostigmine bromide by measuring blood pressure responses and the sensitivity to aromatic hydrocarbons by measuring the activity of hepatic enzymes induced to metabolize these compounds.

2. To treat WKY and SD rats chronically with these compounds and examine behavioral rhythms, temperature rhythms, startle responsiveness, and neuroendocrine function (both basally and in response to stress).

METHODOLOGY: Sprague-Dawley (SD) and Wistar-Kyoto (WKY) rats will be implanted with chronic arterial catheters and then will undergo 3 days of a chronic stress regime. Twenty-four hours after the last stressor exposure, the blood pressure dose-response curves to pyridostigmine bromide will be determined in these rats and unstressed controls. In another set of similar animals, the neuroendocrine and brain c-fos responses to pyridostigmine bromide will be evaluated, as well as the levels of specific isozymes of cytochrome P-450 in the liver. These enzymes are responsible for the metabolism of a large group of xenobiotics, including aromatic hydrocarbons. The changes in these enzyme levels will also be evaluated following stressor exposures and subsequent exposure to aromatic hydrocarbons. Other sets of studies will determine the behavioral and some physiological effects of chronic treatment with pyridostigmine bromide and aromatic hydrocarbons, as well as their effects on the responses to chronic stress.

EXPECTED PRODUCTS (MILESTONES): We expect that chronic stress will persistently increase the sensitivity to pyridostigmine bromide, which might explain how a drug that is used extensively in civilian populations might become toxic under the stresses of the battlefield. We also expect that this effect will be more pronounced in WKY rats, which would show that genetic predisposition might explain why some veterans developed unexplained illnesses and others did not. We expect that hepatic P-450 levels will be inhibited more in WKY rats, and that these results could explain a greater sensitivity to toxins metabolized by these enzymes. Finally, we expect that chronic exposure to pyridostigmine bromide or aromatic hydrocarbons might show long-term effects on behavior or body temperature rhythms which could be very sensitive indices of chronic toxicity.

STATUS/RESULTS TO DATE: We have been unable to validate the behavioral hyperresponsiveness in WKY rats that has been reported by others. However, startle responsiveness and open field activity have been much lower in WKY rats than SD rats, so we will continue to study these 2 strains. In addition, preliminary data suggest that pyridostigmine bromide may cause a substantial decrease in voluntary running activity in rats, but it is unclear as yet whether this could be a long-term effect. However, it is clear that WKY rats are more sensitive to some effects of pyridostigmine bromide than SD rats, but it remains unclear whether these effects will be long-term. These results have set the stage for the proposed studies of interactions among strain, chronic stress, and potential pyridostigmine bromide toxicity. This series of studies will be completed in the spring of 1997, and results will be available in the summer of 1997.

PUBLICATIONS none to date

Title Portland Environmental Hazards Research Center: Environment, Veterans Health and the Gulf War Syndrome. Core Project for Clinical and Epidemiology Research

Research Focus: Symptoms/General Health

Research Type: Epidemiology Research

Agency VA

Study Location VAMC Portland

Study Start Date 10/1/94

Estimated Completion Date 9/30/99

Project Status Ongoing

VA-6

Summary

OVERALL PROJECT OBJECTIVE: To illuminate the relationships between exposures (chemical, physical, stress) and unexplained illness in Gulf War veterans.

SPECIFIC AIMS: 1. To define caseness of unexplained illness in Gulf War veterans; 2. To develop a questionnaire of exposures and effects based on the results of veteran interviews and other relevant data; 3. To conduct a case-control study focused on the spatial-temporal relationship between exposures and illness; 4. To provide subjects for research conducted in Projects I, II and part of IV.

METHODOLOGY: An epidemiological study using a population-based case-control design is being implemented. Pilot work was conducted in two phases before final determination of the research protocol. The first phase consisted of fourteen open-ended interviews with veterans with varying degrees of health and diverse military exposures. The audio-taped interviews are each approximately 3 hours in length. Transcripts of the tapes were analyzed for themes related to knowledge of exposure to diverse chemical, biological, environmental, and psychological factors in the Persian Gulf. In addition, interviewees were asked to provide feedback on specific items being planned for inclusion in the final study questionnaire to promote comprehension and ease in response. The interviews were completed in the Spring of 1995.

The second phase of the pilot work was a feasibility study in which a sample of 422 subjects, randomly chosen from a data tape of Oregon and Washington residents serving in the Persian Gulf, were mailed a survey describing the proposed plan for the large epidemiology study. Specifically, the researchers sought information on potential response rates and barriers to participation. Modifications of the planned research protocol were made based on responses of the feasibility study.

The formal case control study began in November 1995. A random sample of veterans living in the Northwest will receive a mailed study questionnaire containing detailed information on exposures in the Gulf and current health status. The mailing of the survey questionnaire began in mid-November 1995, followed by the case-control clinical evaluations beginning in January 1996. The data base being used for the sampling frame was obtained from the DoD (Defense Manpower Data Center). The database contains the names/addresses of military personnel deployed to the Persian Gulf from August 1990 through July 1991, and listing Oregon or Washington as their home state of record. The accuracy of the addresses in the DoD database has been determined in the feasibility study. Arrangements were made with the Department of Veterans Affairs, NIOSH, and IRS to track individuals with invalid addresses in the DoD file. A small number of addresses have also been obtained from Equifax.

The survey methodology for year two of the funding period has been developed in consultation with Jim Bethel, PhD, Survey Statistician, Westat Inc. Out of approximately 3000 Oregon and SW Washington veterans, 1000 will receive questionnaires in 1995-96. Females and veterans in specific deployment groups (pre-combat, combat, post-combat) have been over-sampled. The first mailing wave to 387 veterans began in November 1995. Respondents to the first mailing wave will provide the selection pool from which the cases and controls agreeing to participate in clinical testing during the months of January-March 1996 will be drawn.

The working case working definition determined at the conclusion of the May 1995 Research Retreat with advisement from external advisory committee is as follows:

Must have at least one of the following signs or symptoms to be defined as a "Case". Onset must
 Persian Gulf Veterans' Illnesses Research Database - Project No VA-6

be during or after deployment to the Persian Gulf. Symptoms must have persisted for one month or longer and have occurred during the three month period preceding the physical examination.

- Muscle/joint pain
- Cognitive changes including memory loss, confusion, inability to concentrate, mood swings, and/or somnolence.
- Diarrhea
- Skin or mucous membrane lesions
- Unexplained fatigue

Healthy controls and cases will be identified from responses to the mailed questionnaire. Cases and controls will be recruited for the medical workup at the Portland VAMC. Cases and controls participating in the clinical workup at the Portland VAMC will also serve as the subjects in Project I and II. In the future, subjects for Project IV will also be recruited from the Epidemiology Core subjects. Multivariate analyses will be conducted to compare subjects with unexplained illness and healthy subjects with respect to exposure to specific environmental factors.

The clinical protocols for the telephone recruitment, histories, physical examination, and testing to be completed on cases and controls have been approved by the Institutional Review Boards of OHSU and Portland VAMC.

EXPECTED PRODUCTS (MILESTONES): Definition of associations, and the strength of those associations, between exposures and unexplained illness

STATUS/RESULTS TO DATE: 1. Open-ended veteran interviews have been completed, transcribed, and summarized. Information gleaned from the interviews was incorporated in the questionnaire content.

2. Feasibility study completed on 422 randomly selected Oregon veterans in the population to be studied. Changes in the design have been implemented as a result of the findings:

- A. Compensation of \$10 will be given to all subjects that complete and return the mailed survey questionnaire.
- B. The first year of survey mailing will focus on residents of Oregon. Initial mailing will be to 500 subjects randomly selected within a 50 mile radius of Portland. Subsequent mailings will be done to different geographic areas of the state. The final survey sampling will be representative of the geographic distribution of all potential subjects in the data base obtained from the DoD.
- C. The mailing of questionnaires to potential subjects in areas outside of Portland will coincide with the negotiation of clinic space in VA facilities in outlying areas of the state. This change is necessary due to the proportion of subjects in the feasibility study that reported that they would not participate in the planned study due to the traveling time to Portland VAMC.
3. Survey sampling plan for 1995-1996 currently being implemented. Questionnaire returns are being scanned for data entry. Incomplete addresses are being tracked. As of August 15, 1996, an estimated 700 questionnaires have been mailed to veterans who served in the Persian Gulf war.
4. Clinical testing of subjects responding to mailed survey began in January 1996. As of August 6, 1996, 101 subjects have been evaluated in the case-control study.

PUBLICATIONS Shortridge LA, Joos S, Redmond, Spencer P, Bourdette D. Potential response bias in epidemiologic studies of Persian Gulf War veterans: American Journal of Public Health (Submitted)

Title Psychosocial, Neuropsychological and Neurobehavioral Assessment (Project I)

Research Focus: Brain & Nervous System

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC Portland

Study Start Date 10/1/94

Estimated Completion Date 9/30/99

Project Status Ongoing

VA-6A

Summary

OVERALL PROJECT OBJECTIVE: To determine if veterans have developed adverse neurobehavioral or psychological effects from service in the Persian Gulf War. If so, to determine the triggering events, including combat stressors, life stressors, chemical exposures, personality disorders, psychological health and motivation to seek compensation

SPECIFIC AIMS: 1. Determine whether veterans have psychological or stress-related disorders; 2. Determine the existence of a dose-effect relationship between neurobehavioral/psychological measures and unexplained illness; 3. Characterize neurobehavioral, neuropsychological, and psychosocial deficits in relation to Gulf War unexplained illness and illness associated with previous conflicts.

METHODOLOGY: Project 1 will determine if veterans of Operation Desert Storm (ODS) have developed any of a broad range of adverse health effects attributable to triggering events during their service in the 1991 Gulf War. The hypothesized triggering events: Combat or life stressors and chemical exposures. Potential factors that could contribute or influence the presence of adverse health effects will be assessed and entered into the analysis, including personality disorders, psychological health, medical conditions, and motivation to seek compensation. Each veteran participating in the overall research program will receive a screening assessment with a 3-hour battery of 18 psychosocial, neuropsychological, and behavioral performance tests. The psychosocial and neuropsychological tests selected for the screening battery required lengthy administration times, offered a bewildering array of administration formats requiring individual explanation, and were in some cases poorly constructed. They have been implemented in a user-friendly and consistent computer-administration format that does not require individual explanation for each test. The entire battery will be piloted in 20-40 veterans to determine timing and acceptability of the final series of tests, and to assist in developing criteria/cut-off scores for selection of candidates for in-depth neuropsychological testing.

Based on screening exam performance, 25 "Cases" and 25 "Referents" per year will receive an in-depth clinical (neuropsychological) interview to more fully characterize apparent disorders. In addition, those initially demonstrating a high level of PTSD will be invited back after 1-2 years to repeat the tests to determine PTSD progression.

Results will be analyzed (a) by skilled clinicians (neuropsychological exam), (b) with multivariate techniques adjusted for confounders (neurobehavioral tests), and (c) with principal components analysis, logistic hierarchical multiple regression, discriminant function analysis, latent growth models analysis, and structural equation modeling to characterize the nature of the psychosocial results.

EXPECTED PRODUCTS (MILESTONES): Develop a predictive model relating the occurrence of unexplained illness to exposure factors.

STATUS/RESULTS TO DATE: Twelve valid, reliable psychosocial tests have been selected for administration in the 4-year cross-sectional study.

PTSD EVALUATION: Penn Inventory for PTSD, Mississippi PTSD Scale, PTSD Checklist;
PSYCHOSOCIAL FACTORS: Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), Substance Abuse Subtle Screen Inventory (SASSI), Life Experience Scale; **PERSONALITY VULNERABILITY:** Positive Affect Negative Affect Scale (PANAS), Minnesota Multiphasic Personality Inventory-II (MMPI-II); **HEALTH SYMPTOMS:** Health Status Questionnaire (SF-36), Hopkins Symptom Checklist (SCL-90R), **WAR ZONE EXPERIENCE:** Combat Exposure Scale,

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revised (CES-r).

A common presentation format was developed for the 12 diverse psychosocial and neuropsychological tests in order to improve acceptability and speed completion, using Supercard software for presentation on a Macintosh laptop computer. The new format includes a spoken test administration option (individually selectable and deselectable at any point in testing) which has been digitally recorded for inclusion with the test presentation system and options to navigate within a test to any question or to repeat the instructions. A training program was also developed to teach veterans to complete the questionnaires, and durable external Response Units (developed in a separately-funded project) have been connected to the laptop computers on which the tests are being presented to up to 8 veterans simultaneously (limited by space limitations). The new testing format (HSS) has been employed with 20 veterans and 10 civilians in pilot evaluations of the prototype training program. The responses from the test subjects were very positive about the testing system, and the mean questionnaire administration time approximated the target of 3 hours in a part of that group (Kovera et al., in press 1996). Changes recommended by respondents were introduced into the HSS. These tests are administered to all subjects tested by the Program's Core unit.

The neurobehavioral tests employed in this project were selected from the Behavioral Research and Assessment System (BARS): ATTENTION, MEMORY, AND LEARNING: Symbol Digit, Digit Span (forward and backward), Selective Attention Test, Serial Digit Learning; RESPONSE SPEED AND COORDINATION: Tapping, Simple Reaction Time; IMPAIRED MOTIVATION: Portland Digit Recognition Test (PDRT).

Most BARS tests were implemented under other funding to the PI of the project, but the PDRT and Tapping tests were prototyped and administered to pilot subjects for this project, including veterans involved in the psychosocial tests, above. The duration of testing met the target time of 60 minutes. These tests are administered to all subjects tested by the Program's Core unit. The test-retest reliability of the 19 tests in the new HSS and BARS computer-implemented formats in the order used in this project was assessed in 60 Oregonians during Summer, 1996.

- PUBLICATIONS** Kovera CA, Anger K, Campbell KA, Binder LM, Storzbach D, Davis, KL, Rohlman DS. Computer-Administration of Questionnaires: A Health Screening System (HSS) Developed for Veterans. *Neurotoxicology and Teratology* (In press).
- Anger WK, Kovera CA, Campbell K, Binder L. A Psychosocial and Neuropsychological Testing Format: the health screening system. Presented at symposium on computerized behavioral testing of humans in neurotoxicology research; Portland, OR, 95

Title Clinical and Neuroendocrine Aspects of Fibromyalgia (Project II)

Research Focus: Immunology

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC Portland

Study Start Date 10/1/94

Estimated Completion Date 9/30/99

Project Status Ongoing

VA-6B

Summary

OVERALL PROJECT OBJECTIVE: Determine the relationship between exposures during the Persian Gulf War and the development of fibromyalgia.

SPECIFIC AIMS: 1. Screen veterans complaining of fatigue and musculoskeletal symptoms with previously developed and validated questionnaires and directed physical examinations to determine if fibromyalgia is present.

2. Correlate the presence or absence of fibromyalgia with possible environmental exposures, as determined in the core part of this program, or with neuropsychological factors, as determined in Project I: Psychosocial, Neuropsychological and Neurobehavioral Assessment.

3. Evaluate a smaller group of veterans with fibromyalgia and an age and sex matched group of veterans without fibromyalgia, for the neuroendocrine abnormalities described in fibromyalgia.

4. Repeat the clinical and neuroendocrine testing on the veterans with fibromyalgia (objective 3) 24-30 months after initial evaluation.

METHODOLOGY: Utilizing the cases determined in the case-control/epidemiological study, using validated methods, screen cases complaining of musculoskeletal complaints for fibromyalgia and controls without symptoms. Perform neuroendocrine testing on both cases and controls.

EXPECTED PRODUCTS (MILESTONES): 1. Determination of the association between exposure to the Persian Gulf War and the development of fibromyalgia; 2. Determine the prevalence of neuroendocrine findings in a primarily male sample; 3. Follow the course of the clinical/neuroendocrine findings with time.

STATUS/RESULTS TO DATE: The planning and coordination of the fibromyalgia study and the core epidemiological study have taken place in year-one. Andre Barkhuizen MD, Arthritis and Rheumatic Disease Fellow, has become the focal clinician responsible for integrating the fibromyalgia clinical study into the epidemiological case-control study. In addition to keeping abreast with national scientific work in the area of fibromyalgia and PGW veterans; preliminary work has consisted of reviewing the Portland Persian Gulf War registry for cases of musculoskeletal pain. The prevalence of complaints in the Portland sample is 29.6% compared to the national registry prevalence of 13.9% and the DoD Comprehensive Clinical Evaluation Protocol reported prevalence of 47%. Results from a pilot population-based survey of 157 veterans eligible for our epidemiologic case-control study indicate that the self-reported rates of musculoskeletal pain in both female and male subjects are both 38%. Responders to the mailed survey who have registered in the PGW registry are two times more likely to report musculoskeletal pain than responders who have not registered.

Investigators have worked closely with the epidemiological core in the development of the items to include in the survey questionnaire, telephone screening questions, and the history and physical examination to be done in the case-control study. Exclusionary diagnoses have been determined. The history and physical examination was pretested on three subjects with musculoskeletal pain in January 1996.

Since commencing the Persian Gulf Research Clinic in January 1996, the majority of subjects have been evaluated by a single examiner for rheumatological conditions. A blinded tender point examination is performed followed by a full rheumatology history and physical examination. The Core laboratory data which include an erythrocyte sedimentation rate, C-reactive protein, antinuclear antibody, rheumatoid factor, hepatitis B, C and human immunodeficiency virus serologies, and selected joint radiographs are reviewed at the bimonthly Clinical Case Review meeting to arrive at a final rheumatological diagnosis. Thus far 57 of the 80 subjects (71%)

admitted to some musculoskeletal complaint on direct questioning in the Persian Gulf Research Clinic. The following is a list of diagnoses (expressed as a percentage of the total clinic sample): mechanical backache 36%, myofascial pain 16%, fibromyalgia 14%, osteoarthritis 6%, tendinitis/bursitis 6%, hypermobility 5%, patellofemoral syndrome 3%, overuse syndrome 3%, inflammatory backache 3% and primary Raynaud's syndrome 1%. Only one subject had an inflammatory condition (a spondyloarthropathy). In 22 subjects (28%) two and occasionally three rheumatological diagnoses were made. In 10 male subjects (13%) with widespread musculoskeletal complaints no clear diagnosis could be made. The majority of subjects with musculoskeletal complaints were on no treatment and were in full-time employment. In the majority of subjects the rheumatological laboratory investigations were normal. Two subjects had a positive antinuclear antibody (titer 1:80 and 1:320) without features of systemic lupus erythematosus. One subject without rheumatological complaints had a positive rheumatoid factor (titer 1:10). No subject had an elevated erythrocyte sedimentation rate or detectable C-reactive protein.

The second component of Project II entails the study of the neuroendocrine axis of the Persian Gulf veterans. All subjects attending the Persian Gulf Research Clinic are screened using the serum Insulin-like Growth Factor-I (IGF-1) and Insulin-like Growth Factor Binding Protein 3 (IGFBP3) levels. This has previously been shown to be reduced in 1/3 of patients with fibromyalgia. In the current study approximately one-third of the Gulf War veterans with fibromyalgia have low levels of IGF-1. Two of the 9 subjects with unexplained muscle and joint pain also have low IGF-1 levels. Further analysis of IGF-1 levels in asymptomatic veterans and those in the other "case" categories will be performed once sufficient numbers are reached.

The final component of the study involves evaluating changes in the neuroendocrine axis of subjects and will commence in August 1996. Twenty cases of fibromyalgia with low IGF-1 levels and twenty control subjects with normal IGF-1 levels will be admitted over the next 2 years for an in-depth study of their hypothalamic-pituitary-growth hormone and hypothalamic-pituitary-adrenal axis. The study protocol has been approved by a peer review committee of the Clinical Research Center – a dedicated research facility at the Oregon Health Sciences University, which is funded and regularly reviewed by scientists and clinicians from the National Institutes of Health. The laboratories of the Clinical Research Center and Oregon Graduate Institute will perform one-half hourly cortisol and growth hormone levels, a 24 hour cortisol production rate and two growth hormone stimulation tests. This will enable the research team to objectively document an altered neuroendocrine stress response and adult growth hormone deficiency in the symptomatic veterans. The altered neuroendocrine stress response will be correlated with the neuropsychological profile and particularly the stress scores collected by Project I. Finally, the stress response will be correlated with exposure to the various environmental agents and the deployment periods of the veterans, which is currently being collected in the Core epidemiology component of the study.

PUBLICATIONS Burckhardt CS, Clark SR, Campbell SM, O'Reilly CA, Bennet RM. Events and co-morbidities associated with the onset of fibromyalgia. Presented at the International Myopain Meeting '95' San Antonio, Texas July 30-August 3, 1995.

Clark SR, Burckhardt CS, Bennett RM. Fibromyalgia patients improve oxygen consumption and pain score during a three month program of aerobic exercise. Presented at the International Myopain Meeting '95' San Antonio, Texas July 30-August 3, 1995.

Bennett RM. "The Fibromyalgia Syndrome" in Textbook of Rheumatology, 5th Edition, Ed. J. Kelly, Harris, Ruddy and Sledge. Ed. DL Goldenberg (In Press).

Title Neurotoxicity of Environmental Pollutants and Warfare Agents (Project III)**Research Focus:** Pyridostigmine Bromide**Research Type:** Basic Research**Agency** VA**Study Location** VAMC Portland**Study Start Date** 10/1/94**Estimated Completion Date** 9/30/99**Project Status** Ongoing

VA-6C

Summary

OVERALL PROJECT OBJECTIVE: To evaluate the neurotoxic potential of a group of hydrocarbon solvents and the effects on cholinergic neurons of long-term exposure to pyridostigmine bromide (PB).

SPECIFIC AIMS: 1. To evaluate effects of pyridostigmine bromide (PB) on cholinergic function in cerebellar and spinal cord explants. 2. To identify the cellular targets of neurotoxic hydrocarbon solvents. 3. To examine the relationship between the chromogenic and neurotoxic properties of selected organic solvents.

METHODOLOGY: Spinal cord-dorsal root ganglia (DRG)-muscle cultures derived from fetal mice are used to study to effects of chronic and acute exposure to pyridostigmine on cholinergic function. Cerebellar cultures derived from newborn mice are used to study the relationship between chromogenic and neurotoxic properties of a group of monocyclic and dicyclic hydrocarbon solvents. The substances to which cultures will be chronically exposed are directly incorporated into the culture medium. The dosage and duration of exposure to pyridostigmine and each of the solvents will be experimentally determined.

Morphological Analyses: Control and treated explant cultures will be stained with thionin (for Nissl substance). This stain allows the evaluation of the various neuronal cell groups present in explant cultures by light microscopy. Central and peripheral myelination can be readily examined in the living state using bright field optics. Immunohistochemical staining will be used to identify alterations of specific neural components (neurofilaments, calbindin), neurotransmitters (choline acetyltransferase, acetylcholinesterase) and supportive glial cells (glial fibrillary acidic protein) induced by neurotoxic compounds. Synaptic changes will be elucidated by electron microscopy. **Electrophysiology:** In spinal cord-DRG-muscle explants, extracellular electrodes are used to record dorsal horn, ventral horn and muscle responses evoked by extracellular stimulation of dorsal and ventral roots. In cerebellar cultures, neurons develop spontaneous activity as they mature in vitro. Extracellular recordings are used to obtain single unit discharge rates and, in combination with extracellular stimulation, are used to assess the efficacy of excitatory and inhibitory synaptic circuitry. Intracellular electrodes are used to study the active and passive properties of individual neurons (motoneurons in the spinal cord cultures and Purkinje cells in cerebellar cultures) and their synaptic responses to afferent stimulation.

Data Analysis: The statistical significance of quantitative data will be evaluated by one way analysis of variance (ANOVA) for each treatment followed by the Tukey HSD (honestly significant difference) test for multiple comparisons, if the data are normally distributed and have equal variances. If the data do not follow a normal distribution, then the nonparametric Kruskal-Wallis test followed by a Mann-Whitney U test will be used for statistical analysis. All statistical evaluation will be done using Systat computer software (SPSS Inc., VA).

EXPECTED PRODUCTS (MILESTONES): Electrophysiological and morphological characterization of the cellular neurotoxicity of selected hydrocarbon solvents and pyridostigmine bromide

STATUS/RESULTS TO DATE: Early results have shown that acute application of PB to spinal cord explants co-cultured with skeletal muscle enhances muscle contractions. This effect is consistent with PB inhibition of acetylcholinesterase and greater availability of acetylcholine at the neuromuscular junction. Long-term exposure of spinal cord explants co-cultured with skeletal muscle causes a progressive decrease of muscle contractions and sensitivity to acetylcholine. Additional morphological and electrophysiological studies are in progress to examine effects of long

term exposure to PB on the neuromuscular junction. Experiments to evaluate the neurotoxic potential of the bromide anion using the same in vitro preparation are also in progress. To date, no noticeable changes in neuromuscular function have been observed following long term exposure (2 weeks) to 10^{-6} M sodium bromide.

PUBLICATIONS Drake-Baumann, R. and F.J. Seil. (1996). Effect of long term anticholinesterase exposure on neuromuscular function in vitro. Soc. Neuroscience Abst. (in press).

Title DNA Damage from Chemical Agents and Its Repair (Project IV)

Research Focus: Environmental
Toxicology

Research Type: Basic Research

Agency VA

Study Location VAMC Portland

Study Start Date 10/1/94

Estimated Completion Date 9/30/99

Project Status Ongoing

VA-6D

Summary

OVERALL PROJECT OBJECTIVE: Determine the long-term consequences of genotoxin exposure on the nervous system of veterans. Of specific interest are nitrogen mustards --- used here as surrogates for culture mustard chemical warfare agents.

SPECIFIC AIMS: 1. Determine the type and quantity of specific DNA adducts and the capacity to repair these adducts in control and nitrogen mustard (NH₂) treated genomic DNA isolated from normal human skin and brain; 2. Determine the type and quantity of specific DNA adducts and the capacity to repair these adducts in genomic DNA isolated from mouse cerebral cortex cultures treated with NH₂; 3. Assess the relationship between DNA damage, DNA repair and cell degeneration in mouse cerebral cortex cultures treated with nitrogen mustard (NH₂); 4. Compare and contrast DNA damage, DNA repair and cytotoxicity in primary neuronal and primary glial cultures treated with nitrogen mustard (NH₂).

METHODOLOGY: Human skin and murine cortical explant cultures will be used to determine the effect of nitrogen mustard (mechlorethamine, NH₂) on genomic DNA. Human skin and mouse cortical explants will be treated for up to 4 days with NH₂, genomic DNA isolated from control and treated explant tissue, and the DNA analyzed for adducts by 32P-postlabeling. For comparative purposes, different nervous tissue cell types (neurons, astrocytes) will be treated with NH₂ to determine the relative sensitivity (DNA damage, cytotoxicity) of specific cells to NH₂ in the nervous system. Findings from these studies will be important for establishing a possible relationship between DNA damage, genotoxin exposure and cytotoxicity of nervous tissue.

EXPECTED PRODUCTS (MILESTONES): 1. We will know whether veterans from the Gulf War have been exposed to chemical agents based upon comparisons between skin tissue obtained from Gulf War veterans and military personnel not engaged in active duty (Biomarkers of previous exposure to a genotoxin); 2. The health status of veterans with regard to their DNA repair profile (protein levels and activity); 3. If chemical warfare agents can induce long-term damage to nervous tissue and produce a spectrum of behavioral symptoms much like those experienced by Gulf War veterans.

STATUS/RESULTS TO DATE: Viability Studies - In vitro cytotoxicity studies were begun to determine if CNS cell types are differentially sensitive to mustards (NH₂). Primary rat cortical astrocyte cultures were treated with various concentrations of mechlorethamine (NH₂). Initial studies indicated that NH₂ was toxic to astrocyte cultures (80% confluency) at concentrations > 50 µM for 1h. In contrast, brief exposure (30 min) of astrocyte cultures to 100 µM NH₂ media and replacement with control media resulted in minimal damage to astrocytes after 24 h. Lower concentrations of NH₂ (0.1-1.0 µM) for 24 h produced minimal damage to astrocytes following incubation of treated cultures with the vital fluorochrome dyes propidium iodide and rhodamine 123 and examined for cytotoxicity by fluorescent microscopy. Astrocytes were more sensitive to low concentrations of NH₂ than human melanoma cells and murine lymphoid cells;

As of August 1996, we have 1) Began study of the response of rat glial cells to nitrogen mustard. Cells proved to be less sensitive to mechlorethamine than human melanoma or murine lymphoid cell lines. 2) Detection of DNA adduct O⁶-methylguanine by immunocytochemical and mass spectrometric techniques. 3) Developed assay for alkyl guanine transferase, a specific repair protein for one type of DNA damage. 4) Probed rat brain for DNA-repair protein levels and activity following treatment with nitrogen mustard. 5) Developed assays for measuring the predominant nitrogen mustard-induced DNA adduct (N⁷-hydroxyethyl guanine, a monofunctional adduct) and

cross-links (difunctional adducts). Obtained authentic N7-hydroxyethyl guanine adduct from Dr. Mark Marino of Walter Reed Hospital to measure this adduct by chromatographic methods. 6) Examined the acute (24 h) and long-term (7 day) cytotoxic effect of nitrogen mustard on human skin tissue (SKIN2). HN2 is acutely toxic to human skin tissue at high concentrations but extensive tissue damage can be induced by concentrations that are 1/10 or 1/100 of the acute dose when tissue is exposed for long periods of time. 7) APE expression (levels and activity) in neuronal and human skin cultures is modulated by HN2. APE levels increased in HN2-treated rodent neuronal cultures (non-dividing cells) while APE levels decreased in human neuronal cultures (dividing cells). APE activity increased in HN2-treated human skin cultures (actively dividing cells). Altered levels and activity of APE may be an indication of HN2-induced DNA damage.

PUBLICATIONS Kisby GE, Sweatt, Spencer PS (1995) Role of DNA repair in protecting mature nervous tissue from DNA damage. J Cell Biochem 21A, 348.

Title Desert Storm Reunion Survey

Research Focus: Brain & Nervous System

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC Boston

Study Start Date 4/1/91

Estimated Completion Date 9/30/95

Project Status Complete

VA-7

Summary

OVERALL PROJECT OBJECTIVE: The Ft. Devens ODS Reunion Survey represents a longitudinal assessment of readjustment of Persian Gulf War veterans returning through Ft. Devens, Massachusetts following their return from the Gulf region.

SPECIFIC AIMS: 1. Describe troop demographics of the Ft. Devens cohort of Persian Gulf War veterans.

2. Examine, both cross-sectionally and longitudinally, family and unit support factors, war-zone exposure, PTSD and psychological distress symptomatology in these veterans.

3. Examine physical health status at Time 2 and explore potential risk factors important in the development of adverse physical health after return from a wartime environment.

METHODOLOGY: Subjects were recruited from a group of approximately 5000 Persian Gulf War veterans who returned home through Ft. Devens, Massachusetts after the Gulf War. The survey at Time 1 constituted a broad range of demographic questions accompanied by an assessment of Post-Traumatic Stress Disorder (PTSD) symptomatology (Mississippi Scale for Combat-related PTSD; Keane, Cadell & Taylor, 1988), general psychological well-being (Brief Symptom Inventory, BSI; Derogatis & Melisaratos, 1983), and combat exposure (Gallop, Laufer & Yager 1981; Rosenheck, 1992), along with queries of other relevant domains including change in work status, current family and social functioning, and post-deployment major life stressors (e.g., death of a loved one, separation or divorce, loss of property, physical or sexual assault) and at Time 2, additional questions were added to further assess psychological health and physical health symptoms. Individual health symptoms were assessed using the 20-item Health Symptom Checklist (Bartone et al., 1989) which asked subjects to indicate the presence and frequency of symptoms over the past several weeks using Likert-type ratings (0=none, 1=a little, 2=often, 3=very often). In addition, subjects were asked to rate their current physical and psychological health separately ('poor', 'fair', 'good', 'very good' or 'excellent') as well as to rate changes in their physical and psychological health since return from the Persian Gulf ('much worse', 'worse', 'same', 'better' or 'much better').

EXPECTED PRODUCTS (MILESTONES): Data from this investigation is expected to provide an important opportunity to examine patterns of readjustment and the factors that contribute to the changes in the years soon after return from a wartime environment. Results from analyses of Time 1 and Time 2 collected data have been published. Publications in progress include evaluation of reported health symptoms by this cohort of Persian Gulf War veterans at Time 2, examination of reported sexual harassment by the women surveyed, and a longitudinal assessment of PTSD and psychological symptomatology between Time 1 and Time 2.

STATUS/RESULTS TO DATE: Over 84 U.S. Army units (n=2949) were surveyed immediately upon their return to Ft. Devens, Massachusetts (Time 1) between April and July 1991. Persons tested at Time 1 represented approximately 60% of the troops that were deployed to the Gulf from that base, and comparisons between this sample and data available for the Ft. Devens military population at large indicate that survey respondents are generally representative of the base's military population. Examination of nonparticipants at Time 1 indicated random absences for administrative and medical purposes. The original cohort contained 2,709 men and 240 women with a mean age of 30.2 years (SD = 8.6) and 13.2 years of education (SD = 1.8). The majority of troops were Caucasian (87.4%) and reservists (52.2% National Guard; 19.9% Army reservists; 27.9% active duty). Active duty troops had more black members and were significantly younger in

age compared to Guard and Reserve Troops. Overall, veterans in the original cohort do not fully reflect military assignments or ethnic and gender compositions of the total U.S. Army or Gulf force (U.S. Government Accounting Office, 1992; communication with Defense Manpower Data Center). Consistent with the Ft. Devens' mission, a higher than average proportion of the original sample had combat support and service support positions during the war, rather than active combat roles. Approximately 18-24 months after initial testing, veterans were resurveyed (Time 2) to reevaluate their adjustment. This survey repeated all Time 1 measures and queried other relevant domains including work status, family and social functioning, health status, health service use, and intervening life stressors. In the majority of cases, the Time 2 survey was readministered in persons during weekend unit drills. Persons in units that could not be scheduled in a timely fashion were resurveyed using an identical questionnaire sent through the mail. A total of 2,313 persons successfully completed the Time 2 survey (2,119 men, 194 women; Wolfe et al., 1993), yielding an overall response rate of 78%. Analyses of these data show no significant Time 1 differences between Time 2 respondents and non-respondents on most background or outcome measures (e.g., educational level, PTSD symptomatology). However, individuals who did not complete the Time 2 reevaluation were more likely to be younger and on active duty status. Based on veterans' verbal and written comments concerning their health status at Time 2, the Time 3 investigation (now Project #1 of the Boston Environmental Hazards Center) was designed to reexamine overall adjustment with a special emphasis on physical health and psychological status and to evaluate cognitive functioning by neuropsychological test methods on a subset of the larger cohort.

- PUBLICATIONS** Wolfe J. Preliminary report of reunion survey on Desert Storm returnees. In: R. Rosenheck, et al. (eds.). War-zone stress among returning Persian Gulf troops: A preliminary report. Legislative report to Congress. 1991.
- Wolfe J, Kelley JM, Busceta ML, Mark WR. Ft. Devens Reunion Survey: Report of Phase I. In: R. Rosenheck et al. (eds.), War-zone stress among returning Persian Gulf troops: Final Report. Legislative report to Congress. 1992.
- Wolfe J, Brown PJ, Kelley JM. Reformulating war stress: Exposure and the Persian Gulf War. *Journal of Social Issues*, 49, 15-31. 1993.

Title Psychological Test Data of Gulf War Veterans Over Time

Research Focus: Brain & Nervous System

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC Mountain Home

Study Start Date 7/9/91

Estimated Completion Date 3/30/97

Project Status Ongoing

VA-8

Summary

OVERALL PROJECT OBJECTIVE: (1) To learn more about reactions to combat exposure, stress, and Persian Gulf War-related health concerns, (2) exploration of the relationships among symptoms, demographic variables and veterans' psychological status, (3) to provide intervention, education, and support to Gulf War veterans by providing a) general information about reactions to combat/desert duty, and b) opportunities for individual discussion of experiences and current physical health, (4) administration of standardized psychological questionnaires and instruments, and (5) referral to VA and other community services available for health and other related concerns. **SPECIFIC AIMS:** To learn more about psychological stress and physical symptoms experienced by Persian Gulf War veterans.

METHODOLOGY: Initially evaluated 66 Gulf War Marine reservists on a number of psychological instruments within 5 months of Operation Desert Storm using the Mississippi Scale for Desert Storm War Zone Personnel, MMPI-2, Impact of Event Scale, War Stress Inventory-Operation Desert Storm Version, Rorschach test evaluation of DSM-III-R criteria for post-traumatic stress and post-traumatic stress disorder (PTSD). At one year follow-up, the MMPI-2 and Impact of Event Scale were collected on a sub-sample of these Gulf War veterans. At 3-year follow-up, all of the original measures, plus a physical symptom questionnaire selected questions from the Persian Gulf Registry Code Sheet and The Hand Test, were administered to a sub-sample of the original group and a control group of Marine Reservists from the same unit who had never been stationed outside of the U.S. Statistical analyses employed in this study included correlation, paired and independent t-tests, ANCOVA, MANCOVA, discriminant analysis, stepwise discriminant analysis, and repeated measure design ANOVA. Currently, volunteers referred for psychological and neuropsychological evaluation will complete all the measures listed above, the Halstead-Reitan Neuropsychological Test Battery, and questions related to disability status.

EXPECTED OUTCOMES: Assess the utility of psychological instruments in the detection of war-zone stress reactions. Instrument variables associated with response to stressors are expected to be related to DSM-III-R criteria for post-traumatic stress and PTSD.

STATUS/RESULTS TO DATE: The project is currently ongoing, the sample size is increasing and data are being collected. Results to date show differences over time between the initial evaluation data and follow-up, and between initial evaluation and control group on selected variables associated acute distress, and capacity for coping. Findings are being analyzed in relation to the assessment, understanding, and treatment of post-traumatic stress symptomatology of PTSD.

PUBLICATIONS Sloan P, Arsenault L, Hilsenroth M, Harvill L, Handler L. (1995). Rorschach measures of post-traumatic stress in Persian Gulf War veterans. *Journal of Personality Assessment*, 64, 397-414.

Sloan P, Arsenault L, Hilsenroth M, Harvill L, Handler L. (1996). Rorschach measures of post-traumatic stress in Persian Gulf War veterans: A 3-year follow-up study. *Journal of Personality Assessment*, 66(1), 54-64.

Sloan P, Arsenault L, Hilsenroth M, Harvill L. (1996). Assessment of non-combat, war-related post-traumatic stress symptomatology: validity of the PK, PS, and IES Scales. *Assessment*, (3)1, 37-41.

Title Evaluation of Cognitive Functioning in Persian Gulf War Veterans Reporting War-related Health Problems

Research Focus: Brain & Nervous System

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC New Orleans

Study Start Date 4/1/94

Estimated Completion Date 9/30/95

Project Status Completed

VA-9

Summary

OVERALL PROJECT OBJECTIVE: Addressing a topic of timeliness and importance, this project evaluated cognitive and psychosocial functioning among Operation Desert Storm (ODS) veterans who experienced health problems and physical symptoms following return from the Persian Gulf War zone. The primary objective of the project is to explore environmental, neurotoxic, and psychological correlates of health complaints among these veterans.

SPECIFIC AIMS: The project examined potential differences between veterans reporting high levels of health concern and those reporting low levels of concern on measures of psychological well-being, psychopathology, environmental exposure to toxins and adverse environmental events in the war-zone and prior to war-zone duty, and neuropsychological functioning.

METHODOLOGY: Conducted in cooperation with a research team of psychologists working at the Boston VAMC, study design incorporated a local sample of 78 Persian Gulf returnees who were divided into high and low health concern subsets on the basis of self-reported health status.

Participants underwent a clinical diagnostic evaluation that includes administration of an environmental exposure interview; a structured psychodiagnostic interview; a battery of neuropsychological tests selected for their specificity and sensitivity to neurotoxicity and emotional and motivational factors; and self-report inventories assessing mood, emotional well-being, PTSD symptomatology, combat exposure, and physical symptoms. Statistical analysis incorporated a multivariate analysis of variance approach, comparing the two health concern subgroups from both sites on measures of environmental exposure, psychological and neuropsychological functioning, and physical symptoms.

EXPECTED PRODUCTS (MILESTONES): Given current interest in the multiple, yet inadequately diagnosed or explained health problems and symptoms reported by sizable subsets of returnees from the Persian Gulf War, this project will have direct relevance to health care delivery in the VA system nationwide. Study results will be pertinent to development of appropriate clinical diagnostic and treatment services for Persian Gulf returnees and veterans of more recent military operations and objective evaluation of veteran disability and compensation claims in the VA system.

STATUS/RESULTS TO DATE: Data collection at New Orleans site has been completed. All data have been forwarded to the Boston site for multi-site statistical analysis.

PUBLICATIONS none to date

Title Memory and Attention in PTSD

Research Focus: Brain & Nervous System

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC New Orleans

Study Start Date 2/1/94

Estimated Completion Date 9/30/98

Project Status Ongoing

VA-10

Summary

OVERALL PROJECT OBJECTIVE: Clinical reports have documented that as many as 67-100% of veterans undergoing treatment for war-related post-traumatic stress disorder (PTSD) exhibit deficits in memory and concentration. This project seeks to address the common and potentially debilitating problems of impaired learning, memory, and attention functions reported by veterans suffering PTSD.

SPECIFIC AIMS: Incorporating two separate investigations, this research applies a comprehensive assessment protocol that includes evaluation of psychopathology and neuropsychological functioning in veterans of Vietnam and a younger cohort of Persian Gulf returnees. In particular, the project will provide in-depth description and analysis of learning, memory, and attention functioning among these veterans.

METHODOLOGY: Within each study, comparisons of neuropsychological performances are conducted between community-recruited groups of veterans with PTSD diagnoses related to war-zone duty, veterans with diagnoses of depression, and veterans found to be free of psychopathology. Psychopathology is assessed with structured clinical interview and self-report inventories. Attention, learning, memory, and other cognitive processes are assessed with standardized neuropsychological assessment instruments. Data analysis, conducted separately for the two cohorts, are accomplished using a multivariate of analysis approach.

EXPECTED PRODUCTS (MILESTONES): Because problems with attention, learning, memory, and other cognitive functions can dramatically disrupt social and occupational functioning, as well as hinder treatment efforts of war-related stress and other disorders, studies of neuropsychological sequelae to war trauma are pivotal to understanding the complex behavioral and emotional expression of PTSD, to delivery of appropriate, effective treatment interventions to these veterans, and to exploring long-term psychosocial outcomes in veterans suffering PTSD and served by the VA system.

STATUS/RESULTS TO DATE: To date, this newly funded research has been conducted on a sample of 95 Persian Gulf returnees. Findings reveal that in comparison to psychopathology-free veterans, veterans diagnosed with PTSD performed significantly more poorly on verbal intellectual tasks including those tasks thought to predict premorbid functioning. Results suggest that intellectual resources, particularly verbal skills, may buffer development of stress-related psychopathology following trauma exposure. Analysis of cognitive data reveal specific deficits in sustained attention, working memory, initial acquisition of new material, and resistance to retroactive interference. Collection of data with Vietnam veterans is ongoing.

PUBLICATIONS none to date

Title Neuropsychological Functioning in Veterans**Research Focus:** Brain & Nervous System**Research Type:** Clinical Epidemiology Research**Agency** VA**Study Location** VAMC New Orleans**Study Start Date** 2/1/92**Estimated Completion Date** 3/1/95**Project Status** Complete

VA-11

Summary

OVERALL PROJECT OBJECTIVE: Complaints of impaired memory and concentration among veterans seeking treatment for post-traumatic stress disorder (PTSD) highlight the importance of systematic evaluation of these cognitive functions among PTSD-diagnosed veterans. The primary objective of this project was to collect pilot data regarding learning, memory, and attention functioning in Persian Gulf returnees reporting PTSD symptomatology.

SPECIFIC AIMS: The specific aim of this project was to compare learning, memory, and attention performances in samples of Persian Gulf returnees with and without diagnoses of PTSD.

METHODOLOGY: Subjects were 15 Persian Gulf War zone veterans diagnosed with military-related PTSD and 27 Persian Gulf War zone veterans found to be free of any PTSD symptomatology. All subjects underwent structured psychiatric interview and neuropsychological assessment using a brief screening battery designed to emphasize attention, learning, and memory functioning. Statistical analyses included a series of univariate analyses of variance (ANOVAs) and univariate analyses of covariance (ANCOVAs) using vocabulary performance as a covariate to compare the two samples on demographic variables and dependent measures of cognitive functioning.

EXPECTED PRODUCTS (MILESTONES): Results of this project impact potentially on comprehensive assessment and treatment services provided to PTSD-diagnosed Persian Gulf War zone veterans.

STATUS/RESULTS TO DATE: Veterans in the PTSD sample were on average older, less educated, and performed more poorly on a vocabulary task used as an estimate of premorbid intellectual sophistication than veterans in the comparison sample. Comparisons of group performances on the neuropsychological tasks revealed that the PTSD sample performed more poorly than the comparison sample on measures of simple and complex attention and word retrieval. When differences in estimated native intellectual skills were controlled for statistically by the inclusion of vocabulary performance as a covariate in a series of ANCOVAs, no significant differences between groups emerged on any of the attention or memory measures. That the effects of PTSD on attention and memory functions could not be parceled out from those attributable to such factors as lower levels of education and premorbid intellectual sophistication does not negate the clinical significance of study findings. Results of this exploratory pilot project complement previous research suggesting that higher levels of education and intellectual functioning may buffer the impact of trauma on the development of subsequent stress-related psychopathology. This phase of the project is complete and has led to the development of a more refined and comprehensive neuropsychological protocol to be administered to a larger sample of Persian Gulf veterans.

PUBLICATIONS Vasterling JJ, Root L, Brailey K, Uddo M, Sutker PB. Attention and Memory performances in post-traumatic stress disorder. Paper presented at 22nd Annual Meeting of the Internat. Neuropsychological Society, Cincinnati, OH. February 1994.

Title Psychological Assessment of Operation Desert Storm Returnees

Research Focus: Brain & Nervous System

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC New Orleans

Study Start Date 8/1/91

Estimated Completion Date 9/1/97

Project Status Ongoing

VA-12

Summary

OVERALL PROJECT OBJECTIVE: This research was designed to determine the psychological sequelae to war-zone exposure among troops who served in the Persian Gulf during Operation Desert Storm (ODS) compared to troops who were activated during ODS but not deployed to the Persian Gulf.

SPECIFIC AIMS: Objectives of this project are to conduct comprehensive psychological assessments and debriefings among the masses of troops mobilized in support of ODS; identify psychological, somatic, and cognitive symptoms and mental disorders, both early and persistent, that are associated with Persian Gulf war-zone exposure; and explore person resource and environment factors that may differentiate Persian Gulf-deployed troops exhibiting war related psychopathology from troops found to be free of psychological disturbances.

METHODOLOGY: Comprehensive psychological assessments were conducted with non treatment seeking troops who served in the Persian Gulf and a comparison sample of troops from the same military units who were activated during ODS but not deployed to the Persian Gulf. Follow up assessments continue for up to five years to assess psychological status over time and ongoing symptomatology. The subject sample to date includes 1520 military personnel mobilized in support of ODS, including 517 Louisiana National Guard and 1003 Marine, Army, Air Force, and Navy Reserve troops, 194 of whom were members of Quartermaster units assigned graves registration duties. Subjects reported an average age of 29 years at time of initial assessment and completed an average of 13 years of formal education. The percentage of African American and other minority troops was 43%, and 14% were women. An assessment battery tapping domains of personal resources, stressor characteristics, negative mood states and traits, psychiatric and physical symptoms, and symptoms of posttraumatic stress disorder (PTSD) was administered in regularly scheduled drill exercises at 6, 8, and 12 months following ODS and at one year follow up intervals. An individually administered comprehensive structured clinical diagnostic interview was conducted with a subset of graves registration troops judged to be at high risk for negative psychological sequelae because of their gruesome Persian Gulf body handling duties. Data analytic strategies for continuous variables included multivariate and univariate analyses of variance, with repeated measures where indicated, and stepwise discriminant function analyses. Chi square analyses were conducted for categorical variables.

EXPECTED PRODUCTS (MILESTONES): By establishing prevalence estimates for negative sequelae to war-zone duty, identifying troops at high risk for development of war zone related psychopathology, and determining factors associated with increased psychological vulnerability to war zone service, results have implications for development of more effective and efficient strategies and procedures for military training and preparing troops for war zone exposure, conducting debriefing exercises to facilitate community reentry following war zone service, and providing mental health treatment interventions specific to war zone related psychopathology.

STATUS/RESULTS TO DATE: The project is ongoing, with follow up assessments planned for five years following initial evaluation and debriefing. Comparisons of data collected upon initial assessment among 876 war zone deployed and 396 non war zone deployed troops showed that troops exposed to war zone duty reported higher levels of depression, anxiety, and somatic preoccupations than did the non war zone deployed sample. Specifically, 23% of the war zone deployed sample showed at least mild levels of clinical depression, and 14% met criteria for PTSD measured by paper and pencil instruments. War zone troops complained more often of somatic

discomfort than did non war zone troops, citing headaches (22% versus 13%), general aches and pains (20% versus 13%), lack of energy (18% versus 12%), sleep disturbances (17% versus 10%), and common cold or flu (16% versus 11 %).

Troops who served in the Persian Gulf described more mental health symptoms as war zone stress severity increased, and symptom expression among 349 war zone troops increased over a 1 year follow up interval on measures of depression, anxiety, anger, physical distress symptoms, and PTSD. Among those who served in the Persian Gulf war zone, ethnic minority troops were more frequently assigned PTSD diagnoses than were their white counterparts; however, women did not evidence greater vulnerability to negative psychological sequelae to war zone exposure than men. War zone related PTSD diagnoses were associated with low levels of the personality hardiness dimension of commitment, reliance on avoidance as a coping mechanism, low perceived family cohesion, and low satisfaction with available social supports.

Comprehensive structured clinical diagnostic interviews were administered to a subset of troops judged to be at high risk for negative psychological outcomes to war zone trauma by virtue of particularly gruesome war-zone assignments, i.e., graves registration or body handling duties, during the Persian Gulf War. Among 24 Louisiana based troops of the 630th Quartermaster Company who performed Persian Gulf graves registration duties, prevalence of current PTSD was found to be 46%, and rates of comorbid disorders among troops assigned PTSD diagnoses included major depression (55%), alcohol abuse/dependence (27%), depressive disorder NOS (18%), and simple phobia (9%). Findings were replicated and extended by assessments conducted among the Puerto Rico based 246th Quartermaster Battalion with subsequent comparisons of 40 troops who performed graves registration duties in the Persian Gulf to 20 similarly trained troops who were not deployed to the Persian Gulf and who had no ODS graves registration exposure. Diagnoses of current PTSD were found in 48% of war zone deployed troops; whereas, none of the non war zone deployed troops met PTSD criteria. Low rates of pre-ODS deployment psychiatric disorders were found in both subsets of troops. Current comorbid diagnoses among troops who met criteria for PTSD included depressive disorder (37%), alcohol dependence (21 %), other anxiety disorder (5%), and polysubstance dependence (5%). One year follow-up assessments were completed with 17 troops of the 630th Quartermaster Company who were assigned Persian Gulf graves registration duties, and 47% met criteria for current PTSD. Of the 26 troops of the 246th Quartermaster Battalion who performed war zone graves registration duties and completed follow up assessment, 38% evidenced current PTSD. Thus, 42% of troops assessed at follow up were classified as positive for PTSD two years after war zone service.

PUBLICATIONS Sutker PB, Uddo M, Brailey K, Allain AN. War-zone trauma and stress-related symptoms in Operation Desert Storm/Shield (ODS) returnees. *Journal of Social Issues*, 49(4), 33-49, 1993.

Sutker P, Uddo M, Brailey K, Allain A, Errera P. Psychological symptoms and psychiatric diagnoses in Operation Desert Storm troops serving graves registration duty. *Journal of Traumatic Stress*, 7, 159-171, 1994.

Sutker P, Uddo M, Brailey K, Vasterling J. Psychopathology in war-zone deployed and nondeployed Operation Desert Storm troops assigned graves registration duties. *Journal of Abnormal Psychology*, 103 (2), 383-390. 1994.

Title Neurobehavioral Aspects of Persian Gulf Experiences: A Pilot Study

Research Focus: Brain & Nervous System

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC Pittsburgh

Study Start Date 4/1/94

Estimated Completion Date 3/31/95

Project Status Complete

VA-13

Summary

OVERALL PROJECT OBJECTIVE: To collect data on a sample of 50 Persian Gulf Veterans who have returned with physical or psychosocial complaints.

SPECIFIC AIMS: To obtain pilot data to gain objective evidence of impairment of cognitive ability and brain function, or of psychosocial disability.

METHODOLOGY: Subjects were tested in our laboratories with an extensive battery of neuropsychological tests, event-related brain potentials, measures of cardiac and pupillary reactivity, laboratory measures of attention, and various interviews, tests, and questionnaires to evaluate psychosocial status with an emphasis of PTSD. Data were analyzed descriptively and in reference to available literature and normative information. The presence of abnormal findings should provide the basis for further study with a controlled investigation.

EXPECTED PRODUCTS: To obtain neuropsychological, psychophysiological and psychosocial data from 50 Persian Gulf veterans.

STATUS RESULTS TO DATE: A paper describing the neuropsychological test results has been accepted for publication in the Journal of the International Neuropsychological Society. The findings are summarized as follows. A neuropsychological investigation of 21 Persian Gulf veterans and 38 demographically matched controls was conducted in order to make a preliminary determination concerning presence of neuropsychological deficits associated with the Persian Gulf War experience. The neuropsychological test battery consisted of measures of complex attention, memory, and motor skills, previously shown to be sensitive to exposure to environmental toxins. It was found that the Persian Gulf veterans group did not demonstrate substantial impairment, but an impairment index derived from 14 test variables was statistically significantly different from controls in the direction of poorer performance. A second study involving the psychophysiological data is currently being prepared for submission to Biological Psychiatry as a brief report. We found prolonged latencies, without reduction in amplitude, in the P300 component of the auditory event related potential (ERP) in the Persian Gulf veterans. This prolongation was significantly different from demographically matched controls when we only considered the 13 of 19 subjects who had complaints related to cognitive function, such as memory impairment. The remaining 6 subjects had normal latencies. Prior research has shown that increased latencies are associated with decline in cognitive efficiency. We therefore concluded that reported cognitive deficits may not be associated with psychological distress alone.

PUBLICATIONS Goldstein G, Beers SR, Morrow L A, Shemansky WJ, Steinhauer SR. A preliminary neuropsychological study of Persian Gulf veterans. Journal of the International Neuropsychological Society. (In press).

Title Vaccine-Mediated Immunity Against Leishmaniasis

Research Focus: Leishmaniasis

Research Type: Basic Research

Agency VA

Study Location VAMC Cleveland

Study Start Date 1/1/93

Estimated Completion Date 9/30/99

Project Status Ongoing

VA-15

Summary

OVERALL PROJECT OBJECTIVE: Vaccine design, with a focus on the use of adjuvants and antigen delivery systems to induce specific T cell responses.

SPECIFIC AIMS: 1. Investigate how different routes of antigen delivery induce different T cell responses; 2. Optimize protective Th1 cell responses to vaccine by manipulation of the in vivo lymphokine environment; 3. Examine the role of accessory cells in lymphocyte activation by targeting recombinant antigen to different classes of APC; 4. Develop vaccination protocols that selectively target antigen to MHC I for optimal activation of CD8+ T cells.

METHODOLOGY: A mouse model of leishmaniasis was used (*L. major*). Both soluble promastigote antigen and recombinant gp63, LACK, and PSA-2 antigens are employed as vaccine immunogens. Current studies are focusing on the use of recombinant interleukin-12 as a vaccine adjuvant and on the use of DNA vaccine techniques. Outcomes to be tested include assessment of whether vaccinated animals are resistant or susceptible to challenge infection and detailed analysis of the T cell phenotype resulting from vaccination. This includes in vivo RNA analysis and ex vivo cytokine production and ELISA assay. The PSA-2 antigen was cloned, sequenced and is being altered by fusion PCR to generate chimeric proteins with functional cytokine and antigen activities. DNA vaccination is being addressed using plasmids that express vaccine antigen with or without IL-2, IL-12, CD40, or B7 costimulatory signals.

EXPECTED PRODUCTS (MILESTONES): We have developed a recombinant PSA-2 antigen for vaccination and are generating recombinant cytokine/antigen fusion proteins for delivery of immunogen and adjuvant in a single molecule.

STATUS/RESULTS TO DATE: Ongoing. Recombinant IL-12 is an effective vaccine adjuvant and overcomes host-defined predispositions towards nonprotective Th2 CD4+ T cell responses. Considerable work on the basic immunology of IL-12 in the murine leishmaniasis model was necessary before pursuing the vaccine-related goals of this grant and these studies generated the bulk of the publications to date.

PUBLICATIONS Heinzel FP, Rerko RM, Ling P, Hakimi J, Schoenhaut DS. 1994. Interleukin 12 is produced in vivo during endotoxemia and stimulates synthesis of interferon- γ . *Infect. Immun.* 62:4244-9.

Heinzel FP. 1994. Interleukin 12 and the regulation of CD4+ T cell subset responses during murine leishmaniasis. *Parasitol. Today.* 10:190-2.

Heinzel FP, Schoenhaut D, Rerko R, Roesser L, Gately M. 1993. Recombinant murine IL-12 cures infection with *Leishmania major* in susceptible mice. *J. Exp. Med.* 177:1505-1509.

Title Protective Immunity in Experimental Visceral Leishmaniasis

Research Focus: Leishmaniasis

Research Type: Basic Research

Agency VA

Study Location VAMC San Antonio

Study Start Date 10/1/94

Estimated Completion Date 9/30/97

Project Status Ongoing

VA-16

Summary

OVERALL PROJECT OBJECTIVE: Characterization of the protective immune mechanisms in experimental visceral leishmania, and identification of the parasite antigens which elicit such protective responses.

SPECIFIC AIMS: Studies of the murine model of visceral leishmaniasis will provide a means to characterize the operative protective immune mechanisms as well as identify parasite antigens which have potential use for human vaccination. Characterization of the protective immune mechanisms in experimental visceral leishmaniasis will be accomplished by studies of the *in situ* cytokine response to primary infection in susceptible mice, as well as identification of responses associated with the acquisition of immunity. Once the mechanisms associated with protective immunity have been defined the parasite antigens relevant to immunity can be identified. Purified and recombinant *Leishmania donovani* antigens which elicit an *in vitro* cytokine response which correlates with *in vivo* immunity will be identified and characterized.

METHODOLOGY: The murine model of visceral leishmaniasis will be used to characterize the mechanisms involved in protective immunity at the tissue level. These studies will be performed using a reverse transcriptase polymerase chain reaction methodology for measuring cytokine (IL 4, IL 6, IL 10, IL 12, IFN γ , TNF α , and TGF β) gene expression in skin, lymph node, and spleen. Comparisons will be made between naive (susceptible) and immunized (resistant) mice. Once the *in situ* mechanisms are better defined, *in vitro* correlates of immunity (e.g. a certain cytokine profile) can be identified. Semipurified or purified soluble antigens will then be tested *in vitro* for their capacity to elicit a proliferative response and protective cytokine profile in splenocytes or lymph nodes. A recombinant library will also be directly screened using spleen cells from immune animals. This will enable the identification of vaccine candidates which can subsequently be tested in the animal model.

EXPECTED PRODUCTS (MILESTONES):

1. Identification of cytokines associated with control of infection
2. Identification of cytokines associated with resistance to re infection
3. Identification of antigens having the potential to stimulate protective immunity

STATUS/RESULTS TO DATE: Mice infected with *L. donovani* amastigotes by the intradermal route develop minimal cutaneous swelling, regional lymphadenopathy, but no detectable visceral (hepatic) parasite burden. In contrast, mice infected by the intravenous route develop progressive hepatosplenomegaly and a visceral parasite burden that increases up to 4-6 weeks after infection. To understand the mechanisms associated with the local control of infection we have characterized the *in situ* expression of cytokines (IFN- γ , IL-4, IL-10, and IL-12) in the spleen, draining lymph node, and cutaneous site of inoculation using quantitative reverse transcriptase-polymerase chain reaction methods. There appears to be considerably greater expression of IFN- γ and IL-12p40 in the draining lymph node following cutaneous inoculation compared to the spleen, but was greater in LN. There was significant expression of both IL-10 and IL-12 at the cutaneous site of inoculation starting 7 days after infection. Thus there seems to be a mixed Th1/Th2 type response to primary infection in this model, but local control (skin and draining LN) appears to be associated with markedly increased levels of IFN- γ and IL-12 RNA. These differences may be due to more efficient antigen presentation at the LN level following cutaneous infection (possibly from migration of cutaneous Langerhans cells), or the induction of immunological tolerance following intravenous infection. Studies to further define the mechanisms involved are in the progress.

PUBLICATIONS none to date

(blank)

Title Immunological Evaluation of Persian Gulf Veterans

Research Focus: Immunology

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC Birmingham

Study Start Date 4/1/94

Estimated Completion Date 5/1/95

Project Status Complete

VA-17

Summary

OVERALL PROJECT OBJECTIVE: To understand possible contributions of immunological abnormalities to disease manifestations in Persian Gulf War veterans. The chief complaints of these veterans include arthralgias and central nervous system dysfunctions, i.e., disorders which may have a common immunological basis. The intent of this proposal is to expand upon ongoing medical and neurobehavioral analyses of veterans from the Birmingham VA Medical Center to include an immunologic component in the evaluation of these veterans.

SPECIFIC AIMS: Evaluate potential changes in the immunological status of Persian Gulf War veterans using sensitive biological assays of immune cellular function such as those previously described for use in evaluating chemical sensitivities.

METHODOLOGY: Functional immune integrity of peripheral blood mononuclear cells was tested in subjects (approximately 50) and age- and sex-matched controls (approximately 10). Longitudinal samples were obtained from 2 subjects. Antigenic and mitogenic responses were determined using the recall antigen tetanus toxoid and the T-cell mitogen phytohemagglutinin. Proliferative responses were measured by tritiated thymidine uptake and compared with cultures of unstimulated subject or control cells. Data were reduced and statistically compared using a two-sample, unpaired t test.

STATUS/RESULTS TO DATE: The final number of samples analyzed for immune function in mitogen-induced and antigen-induced proliferative assays included approximately 40 Persian Gulf veterans and 7 age- and sex-matched controls. When these two groups were compared for mitogenic responses, no significant difference was noted ($p > 0.06$). This finding suggested that the subjects and controls had similar T cell function potential since the phytohemagglutinin mitogen is a polyclonal stimulant used to assess potential for T cell responses. However, when these two groups were compared for antigenic response using the tetanus toxoid recall antigen, a significant difference was noted ($p = 0.027$). With less than 50 subjects and less than 10 - 15 controls, these data are to be viewed and interpreted only as preliminary findings suggestive of a difference in recall response to antigenic stimulation. More subjects are needed prior to publication or dissemination of these preliminary findings.

PUBLICATIONS none to date

Title Chronic Gastrointestinal Illness in Persian Gulf Veterans

Research Focus: Miscellaneous

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC Boston

Study Start Date 10/1/94

Estimated Completion Date 10/1/96

Project Status Ongoing

VA-18

Summary

OVERALL PROJECT OBJECTIVE: Clearly define the most prevalent chronic gastrointestinal symptoms in a unit of Persian Gulf veterans.

SPECIFIC AIMS: 1. Determine and define symptom complex. 2. Look for underlying pathophysiology.

METHODOLOGY: Survey of a single unit of Persian Gulf veterans. Hydrogen breath tests on affected individuals.

EXPECTED PRODUCTS (MILESTONES): Ultimately to identify pathophysiology of the gastrointestinal symptoms.

STATUS/RESULTS TO DATE: Survey completed. Have identified most prevalent symptoms.

Note: Following is quoted from poster accepted for Poster Presentation at Digestive Disease week in San Diego, May 1995, Chronic Gastrointestinal Symptoms In Persian Gulf Veterans; MB Sostek, S Jackson, JK Linevsky, EM Schimmel, BG Fincke; Departments of Medicine and Social Services, Boston Veterans Affairs Medical Center and Boston University School of Medicine, Boston, MA.

Background: Persian Gulf Syndrome is characterized by a constellation of chronic symptoms postdating deployment to the Gulf Region in 1991. Intermittent diarrhea is one of the eight most commonly reported symptoms. The prevalence of non-diarrheal gastrointestinal (GI) symptoms is not well documented. Over the past year, we have received increasing referrals for evaluation of Persian Gulf veterans (PGV) with various GI complaints. The aims of this study were I) to determine the prevalence and spectrum of GI complaints in a representative sample from this population and II) to compare this data to a control group of soldiers not deployed to the Gulf region.

Methods: A 4-page questionnaire was mailed to the 92 members of a National Guard Unit deployed to the Persian Gulf Region in 1991 and distributed to 44 members (controls) of the same unit who were not deployed to the Gulf Region in 1991. The questionnaire asked the veterans to grade current severity of 26 GI and 10 non-GI symptoms. The survey also asked veterans to recall occurrence of 5 GI symptoms either during or before the Desert Storm mission.

Results: 57/92 Persian Gulf veterans (62%) responded to the survey. All 44 of the controls returned the survey. The table below summarized the reported frequency of several GI symptoms in this population:

GI Symptom	Before ODS	After ODS	Controls (Current)
Loose Stool	2/57 (3%)	39/57 (68%)*	4/44 (9%)
Abdominal Pain	2/57 (3%)	32/57 (56%)*	3/44 (7%)
Excessive Gas	5/57 (9%)	42/57 (74%)*	10/44 (23%)
Nausea/Vomiting	2/57 (3%)	13/57 (23%)	1/44 (2%)
Hematochezia	no data	4/57 (7%)	0/44 (0%)

*p<.0001 compared to symptom frequency before desert storm.

Additional frequently reported GI symptoms among PGV's in this survey include: sensation of incomplete rectal evacuation post defecation 34/57 (60%), and watery bowel movements following episodes of abdominal pain 30/57 (53%). The most frequent non-GI symptoms were: fatigue 46/57 (81%), joint pains 42/57 (74%) and headache 38/57 (67%).

Conclusion: A significant number of veterans from a single National Guard unit, deployed to the Persian Gulf, developed GI symptoms while in that region. The majority of these veterans currently continue to report persistent loose stools, lower abdominal pain, excessive gas and tenesmus. Veterans in the same unit, who were not deployed to the Gulf region, report significantly fewer chronic GI symptoms at the present time. While these symptoms are suggestive of the

development of irritable bowel syndrome following Persian Gulf deployment, further studies are needed to better understand the pathophysiology of this combination of chronic GI symptoms.

PUBLICATIONS Abstract accepted for Poster Presentation at Digestive Disease week in San Diego, May 1995.

Sostek M. High prevalence of chronic gastrointestinal symptoms in a national guard unit of Persian Gulf veterans. Accepted to the Am J of Gastroent. Dec. 1996

Title Psychological Adjustment in Operation Desert Shield/Storm Veterans

Research Focus: Brain & Nervous System

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC Gainesville

Study Start Date 7/1/91

Estimated Completion Date 7/1/93

Project Status Complete

VA-20

Summary

OVERALL PROJECT OBJECTIVE: The study examined the psychological effects of military service in the Persian Gulf during Operation Desert Shield/Storm.

SPECIFIC AIMS: Noncombat reserve and national guard troops who were in the Persian Gulf were compared to activated and nonactivated troops who remained in the United States during the Persian Gulf War. The study determined the difference between the three groups in terms of psychological adjustment and impact on cognitions and feelings about the war.

METHODOLOGY: Subjects were 507 members of National Guard and Reserve units in Northcentral Florida. Data was collected over a two-month time period from July 29 to September 23, 1991. Thus, the data was collected approximately 6 months after the ground war ended, and usually from one to two months after the troops had returned to the United States. Data was collected during the customary monthly weekend drills, and with the endorsement of the units' commanders. For units that had been deployed to the Persian Gulf, troops were also briefed about the potential emotional and family problems associated with post-war adjustment, were provided with information about veterans benefits, and were advised of the availability of readjustment counseling in our VAMC and other facilities in their communities. The order of presentation of these elements of necessity varied from site to site, and sometimes within a site, as it was imperative to oblige the needs of the units' and those of others involved (e.g. Vet Center counselors, veterans benefits counselors).

Subjects were assured of the anonymity of their responses, and were instructed to hand their packets of questionnaires directly to the study's investigators, in an attempt to assuage subjects' concerns that their careers might be jeopardized by their disclosures. However, it is evident that doubts lingered, as some subjects commented on their concerns about how the results might be used, and many failed to provide their names (requested in order to conduct follow-up). Six troops omitted information about their gender as well, and were thus excluded from analysis.

The subjects, tested at different sites, consisted entirely of combat support troops, including engineering units, mobile medical units, transportation units, military police, a quartermaster unit, and a demolition unit. Of the 507 troops included as subjects, 397 were male and 110 were female. Although a minority in the other units, females made up about 50% of the mobile medical units. For the purpose of analysis, subjects are categorized as deployed (i.e. activated and sent to the Persian Gulf during Operation Desert Storm/Shield), activated/not deployed (activated for duty during Operation Desert Storm/Shield but serving in the United States) and not activated (remaining on non-active status throughout Operation Desert Storm/Shield).

	Males	Females
Deployed	213	75
Not Activated	173	26
Activated/Not Deployed	11	9

Due to the low numbers currently available in the Activated/Not Deployed category, the analysis is restricted to Deployed and Not Activated.

Unit officers provided strong encouragement to their troops to participate in the study, and although it is not possible to know exactly what percentage did actually participate, 90% would be a reasonable estimate. Of those subjects that did return their questionnaire packets, many did not complete the entire protocol, which normally required about one hour to complete. The questionnaires were presented in the following order: 1) demographic questionnaire, 2) combat

exposure scale from the War Stress Interview, 3) SCL-90 plus 15 additional items from the Cincinnati Stress Reaction Scales, 4) Gainesville Readjustment Questionnaire, 5) Family Environment Scale, 6) Impact of Events Scale, 7) Work Environment Scale.

RESULTS: Analysis of the data indicated that individuals deployed to the Persian Gulf differed significantly from individuals in reserve and guard units who were not activated during ODS. Specifically, they reported a greater degree of intrusion and avoidance symptoms related to the war, as measured by the IES. ODS veterans who were also veterans of prior wars reported fewer intrusion and avoidance symptoms. Age was not found to be a significant factor. The scores on the Gainesville Questionnaire, postulated to indicate enhanced coping strategies, did not correlate significantly with evidence of superior mental health on the SCL-90-R or the IES. A lack of significant difference between ODS veterans and control group in terms of SCL-90-R scores suggests that the overall psychological health of most of the ODS veterans does not appear to have been affected by the war. However, it is apparent that some subjects had lingering doubts about the possible repercussions of admitting problems, and this is likely to have suppressed some of the SCL-90-R scores, which showed less pathology than non-patient norms in the general population. Additionally, the units available to this investigation were all combat support units, and combat exposure was consequently more limited and less severe than for combat units. Only 156 subjects returned follow-up data, with only 27 completing all 3 follow-ups. An ANOVA conducted to determine if the follow-up group was representative of the larger population resulted in a significant interaction effect, in which ODS veterans who cooperated with the follow-up admitting to higher intrusion and avoidance symptoms on their initial testing. Thus, the follow-up data was concluded to not represent a random sample of the desired population. One subject found the mailed follow-up questionnaires caused discomfort and indicated that she did not want to be contacted further. We abided by her request. No other adverse effects were noted.

PUBLICATIONS Returning Persian Gulf Troops: First Year Findings, published by Northeast Program Evaluation Center (NEPEC), VAMC, West Haven, Connecticut, 1992.

Title A Comparison of PTSD Symptomatology among Three Army Medical Units Involved in ODS

Research Focus: Brain & Nervous System

Research Type: Clinical Epidemiology Research

Agency VA

Study Location VAMC Phoenix

Study Start Date 1/8/92

Estimated Completion Date 12/3/94

Project Status Complete

VA-21

Summary

OVERALL PROJECT OBJECTIVE: The objective of the study was to compare three Arizona Reserve Medical Units involved in Operation Desert Storm on PTSD symptomatology one year after the war utilizing the revised Mississippi Scale for Combat-Related PTSD (Keane, Caddell, and Taylor, 1988). One of the groups was deployed to Saudi Arabia (N=42), one to England (N=37), and one to Arizona (N=17).

SPECIFIC AIMS: The hypothesis was that the group deployed to Saudi Arabia would have significantly higher scores than the other two groups.

METHODOLOGY: Subjects consisted of three Arizona Military Reserve Medical Units, one deployed to Saudi Arabia, one deployed to England and one deployed locally. Members of all units included physicians, nurses and other medical specialists.

The group deployed to Arizona (AZ) consisted of 17 subjects, 10 females (58.8%) and 7 males (41.2%). Of the 13 subjects in AZ who provided demographic data, 2 were age 20-29 (15.4%), 5 were 30 to 39 (38.5%), and 6 were 40 to 50 (46.2%). Ages ranged from 20 to 54. The mean age was 38.9. Mean age for females was 34.7. Mean age for males was 43.1.

The group deployed to England (ENG) consisted of 37 subjects, 21 females (56.8%) and 16 males (43.2%). Eleven were age 20-29 (29.7%), 14 were 30 to 39 (37.8%), 9 were 40 to 49 (24.3%), and 1 was 50 to 59 (2.7%). Ages ranged from 21 to 56. The mean age was 33.7. Mean age for females was 34.4. Mean age for males was 33.

The group deployed to Saudi Arabia (SA) consisted of 42 subjects, 20 females (47.6%) and 22 males (52.4%). Twelve subjects were age 20-29 (28.6%), 10 were 30-39 (23.8%), 15 were 40-50 (35.7%) and 5 were 50-59 (11.9%). Ages ranged from 21 to 56. The mean age was 37. Mean age for females was 35.8. Mean age for males was 38.1. Design, Procedures, and Instruments. These data were collected in the first half of 1992, approximately one year after the end of the Persian Gulf War. At a regular monthly unit meeting, consenting subjects were administered the current revision of the Mississippi Scale for Combat-Related PTSD (Keane, Caddell and Taylor, 1988) and a questionnaire on demographics, substance abuse and effects on family. The validity and reliability of the Mississippi Scale have been established by Keane, Caddell and Taylor (1988). Subjects were invited to write additional comments about the impact of the war and were given an opportunity to volunteer to be interviewed.

The purpose and procedures of the study were described to subjects, and they were informed that they could withdraw from the study at any time prior to publication. They were also informed that participation or refusal to participate will not affect their military careers or subsequent benefits. All responses remained confidential. Data were identified by codes rather than names.

Mississippi Scale means of the three groups were analyzed by a one-way Analysis of Variance. The Scheffe Test of Multiple Comparisons was performed post hoc. Subjects' written comments, as well as responses regarding drug and alcohol use, were compiled and summarized but not statistically analyzed. The Semi-Structured Initial Interview for Desert Storm War-Zone Personnel (Litz, Knight, Wolfe, Kaloupek, Quinn, Krinsley, Fisher, Weathers, & Keane, 1991) was administered to ten members of SA by one of the authors. The authors analyzed the data for common themes. Interviewees' descriptions of war-zone stressors are reported in the results section of the paper.

Table 1

Demographics of Interviewees (N=10)

Persian Gulf Veterans' Illnesses Research Database - Project No VA-21

Variable	Males (N=3)	Females (N=7)
Mean age	48.6	39.9
Age range	45-52	22-50
Marital status		
Married	3	4
Single	--	3
Military rank		
Officer	2	5
Enlisted	1	2
Education		
Doctorate	1	--
Masters	--	2
Bachelors	--	2
Some college	2	3
Race		
Caucasian	3	7

RESULTS: Analysis of Mississippi Scale Scores

A one-way Analysis of Variance revealed a significant difference in Mississippi Scale scores among the three groups ($p < .001$). Post hoc analyses revealed that the mean score of the unit deployed to Saudi Arabia (SA) ($M = 83.98$) was significantly higher than that of the unit deployed to England (ENG) ($M = 73.61$) and the unit deployed to Arizona (AZ) ($M = 73.61$), $F(2, 103) = 9.83$, $p < .001$. Also, ENG obtained significantly higher scores than AZ. Means, standard deviations and test results are presented in Tables 3, 4 and 5.

Table 3: Means and Standard Deviations

	Mean	SD	N
SA	83.97	19.58	43
ENG	73.6	15.88	38
AZ	66.00	11.43	25

Table 4: Analysis of Variance

Effect	SS	df	MS	F	p
VAR1	5453.91	2	2726.954	9.83	.001
Within	28570.06	103	277.379	--	--

Table 5: Post hoc Comparison: Scheffe Test: p-levels
marginal means for indep. var.

	AZ	ENG	SA
mean=66.00 level code:	AZ	X	0.178
mean=73.61 level code:	ENG	0.178	X
mean=83.98 level code:	SA	0.00	0.04

Six SA subjects (14%) scored greater than 107, the cutoff score for the diagnosis of PTSD. One of those subjects wrote on the questionnaire that he believed that his distress was caused by his Vietnam experience rather than his ODS experience. One subject in ENG scored over 107 (2.7%).

War-Zone Stressors of SA as Described by Interviewees. The unit arrived in Dhahran, Saudi Arabia, on January 4, 1991 and was evacuated on April 4, 1991. Initially billeted in Al Khobar, near the Dhahran Air Base, they were in Al Khobar when the SCUD missile hit. As medical personnel, they were not allowed to carry weapons according to the Geneva Convention, but they were required to pull guard duty both in Dhahran and in the field. They were responsible for setting up their own combat support hospital 10 miles north of the Iraqi border. The closest support hospital to the front lines, they were married with a helicopter unit and received 32% of the war's casualties from both Allied and Iraqi forces. Specific casualties were seen as especially stressful: The first female casualty, abandoned Iraqi children for whom they had no pediatric instruments, and a nurse and physician who were killed when the Claymore mines they had gathered as souvenirs exploded. Nine subjects feared for their lives. Seven said the SCUD missile landing was highly stressful. Two women found the casualties, particularly women and children, extremely stressful. Others said the

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casualties were not particularly stressful because they saw severe injuries in their daily work. Noncombat War-Zone Stressors. All subjects said that they were anxious and/or bored waiting for war to begin. Worries included fear of dying, chemical warfare, the morality of the war, and welfare of family members at home or serving in Saudi Arabia. Six subjects mentioned cultural or environmental stressors. A Jewish man feared torture if taken prisoner. Two women said Saudi men touched them and/or made sexual comments. A woman feared "crazy" Saudi drivers. Two women and two men spoke of heat and the "endless" and "dark" desert. Other stressors were relationships with other unit members, distrust of leaders, poor sanitation, and physical labor. Deployment and Homecoming Stressors. Deployment stressors included anxiety about leaving family members and disruption of careers. Three women mentioned leaving children as the hardest thing they had ever done. One woman worried about her aging mother. Homecoming stressors included physical problems and changes in relationships and careers. Three women said that readjustment was more difficult than they had anticipated. A man divorced after the war. A woman had to start over in school. One woman attributed symptoms of diarrhea, fatigue, and irritability to a "parasite". Another had carpal tunnel. All subjects denied exacerbation of previous traumas. Coping Strategies. Subjects coped with stress by talking to friends, relying on religious faith, reading, calling or writing home, self-talk (e.g., "Calm down." "It will be all right."), playing cards, keeping busy/exercise/physical labor, shopping, joking, eating, writing a journal, remembering home, and romance.

Several subjects compared coping strategies of men and women. One woman said that women were supportive of one another and thus had fewer emotional problems than men. Another woman said women talked easily and could cry. She said, "Maybe it seems like you're hysterical, but then you feel better. You get hugged when you cry." She said women negotiated assignments if they didn't get along with tentmates; men accepted assignments they didn't like. She noted that both soldiers who were evacuated were men. A man stated that men "adjusted better" while the women "complained about access to phones and filth and not getting mail. The older the nurse, the more bitching."

Some interviewees compared coping strategies of younger soldiers and older soldiers. Three women in their forties and a 49 year old man stated that younger soldiers had more trouble coping than older ones. Older soldiers "laughed a lot, read a lot, played bridge, [and] didn't dwell on" troubles. The man and two of the women said the younger members engaged in sex to cope with stress. One woman noticed that younger soldiers who coped best kept active. Two women noted that some unit members drank alcohol to cope.

Lasting Psychological Impact of the War. Positive effects of the war included greater faith in self, lasting friends, pride in accomplishments, adventure, and a greater sense of purpose.

Only one subject approached full PTSD. She had a flashback while working in the emergency room and still reacted to loud noises. One man said he had not slept through the night since the war. One woman was emotionally numb. One man was avoidant.

Several interviewees thought that members most affected by the war had quit the Reserves.

Several thought that people who had served in Vietnam were more distressed by ODS than other members. A nurse who served in both wars said that better facilities made Vietnam "easier"; "primitive" conditions made ODS very stressful.

Common Themes of Structured Interviews (N=10)

Stressor	Number of Subjects	Women	Men
Afraid of dying	10 (100%)	7	3
SCUD landing	7 (70%)	5	2
Seeing severe casualties	2 (20%)	2	0
Waiting for war to begin	10 (100%)	7	3
Cultural/Environmental factors	6 (60%)	3	3
Interpersonal relations	3 (30%)	1	2
Distrust of leaders	3 (30%)	2	1
Hard physical labor	2 (20%)	1	1
Poor sanitation	3 (30%)	3	1

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Leaving children	3 (30%)	3	0
Leaving other family members	1 (10%)	1	0
Relationship and/or career disruption	5 (50%)	4	1
War-related physical problems	2 (20%)	2	0
Coping Strategies			
Talking to friends	6 (60%)	4	2
Religion	4 (40%)	3	1
Reading	4 (40%)	2	2
Calling/Writing home	3 (30%)	2	1
Exercise/Physical Labor	3 (30%)	2	1
Self-talk (e.g., "calm down", "I'm all right")	3 (30%)	3	0
Shopping	2 (20%)	1	1
Joking	2 (20%)	1	1
Eating	1 (20%)	1	1
Writing a journal	1 (10%)	1	0
Remembering home	1 (10%)	0	1
Romance	1 (10%)	0	1
Lasting Psychological Impact (At the time of the study)			
Positive effects	6 (60%)	5	1
Confidence/Pride/Purpose	4 (40%)	3	1
Lasting friends	3 (30%)	2	1
Adventure	2 (20%)	1	1
PTSD Symptoms	4 (40%)	2	2
Intrusive thoughts	1 (10%)	1	—
Startle response	1 (10%)	1	—
Sleep disturbance	1 (10%)	—	1
Emotional numbing	1 (10%)	1	—
Flashbacks	1 (10%)	1	—
Avoidance	1 (10%)	—	1

PUBLICATIONS none to date

Title Female Gender and Other Potential Predictors of Functional Health Status Among Persian Gulf War Veterans

Research Focus: Brain & Nervous System

Research Type: Epidemiology Research

Agency VA

Study Location VAMC Boston

Study Start Date 9/11/95

Estimated Completion Date 3/19/98

Project Status Ongoing

Project Status VA-30

Summary

OVERALL PROJECT OBJECTIVE: The primary objective of this study is to identify and describe the effects of potential predictors on the functional health status and health perceptions of male and female veterans approximately four years after their deployment to the Persian Gulf; and to examine if and how identified risk factors differ between female and male veterans. A secondary objective of the proposed project is to ascertain the prevalence of multiple chemical sensitivity (MCS)-like symptoms reported among this population, and to explore risk factors for the development of this syndrome.

SPECIFIC AIMS: The more specific goal of this study is to use the obtained data to significantly advance DoD screening and intervention efforts aimed at enhancing positive military and post-deployment adaptation among soldiers, especially women. With women's rapidly increasing representation in the U.S. Armed Forces, there is a pressing need to investigate these relationships, and to understand factors that might be distinctively associated with women's well-being, both during and following war-time deployment.

METHODOLOGY: By using cross-sectional and longitudinal data from an existing, carefully followed military cohort and by expanding predefined measures of health symptoms, and health perceptions, this investigation is conducting analyses that focus directly on: (a) defining the set of reported environmental and psychosocial combat-theater exposures and physical health variables associated with female and male soldiers recent deployment; and, (b) describing the relationship of these variables to functional status and self-reported physical health. A primary emphasis is on investigating the role or impact of gender, specifically, whether female gender is a significant factor in predicting either functional health status or health perceptions. Data analyses will proceed through a series of three major stages. The initial stage involves generation of descriptive analyses for all variables of interest and will permit comparison of responses between women and men. The second stage involves the determination of bivariate odds ratios of gender, PTSD diagnostic status, and environmental exposure on functional health status. The third stage involves multivariate regression procedures to examine the effects of gender, PTSD and reported environmental exposure on functional status and on self-reported health.

In addition, an exploratory analysis will be conducted of the comprehensive symptom review results with respect to the diagnosis of Multiple Chemical Sensitivity. One of the first steps in ascertaining the prevalence of MCS-like symptoms among our study population is developing a survey instrument that can be used to identify subjects with MCS-like symptoms. To date, there is only one survey instrument that has been validated to assess MCS symptoms. However, due to its length, we are currently testing the validity of a shortened version of this existing questionnaire on patients referred to the Massachusetts Respiratory Hospital, and controls recruited by participating patients. Depending on the prevalence of individuals who meet criteria for MCS-like symptoms, multivariate models similar to those for functional status with MCS-like symptoms as the dependent variable will be conducted.

EXPECTED PRODUCTS (MILESTONES): To develop a shorter questionnaire than the one currently used to identify MCS, scientific publications on Persian Gulf War illnesses (including the impact of stress and trauma on outcome, annual reports, gender models of health outcomes.

STATUS/RESULTS TO DATE: The shortened MCS questionnaire has been distributed to subjects. The larger survey instrument is currently being piloted and will soon be mailed.

- PUBLICATIONS Proctor SP, Wolfe J, Friedman M. Evaluation of health symptoms reported by Gulf War veterans. Paper presented at the Annual Meeting of the International Society for Environmental Epidemiology, Research Triangle Park, NC. September 1994.
- Wolfe J, Brown PJ, Bucsela ML. Symptom responses of female Vietnam veterans to Operation Desert Storm. *American Journal of Psychiatry*, 149, 676-679, 1992.
- Wolfe J, Brown P, Kelley J. Reassessing war stress: exposure and the Gulf War. *Journal of Social Issues*, 49, 15-31, 1993.

Title Stress Symptoms and Their Causal Attribution in Desert Storm Veterans

Research Focus: Brain & Nervous
System

Research Type: Epidemiology Research

Agency VA

Study Location VAMC Clarksburg

Study Start Date 12/1/95

Estimated Completion Date 12/31/96

Project Status Ongoing

VA-36

Summary

OVERALL PROJECT OBJECTIVE: Describe motivational aspects of stress in relationship to war experience.

SPECIFIC AIMS: Determine stress symptoms and their causal attribution in Desert Storm veterans.

METHODOLOGY: Survey Methodology: Mail out to 200 randomly selected subjects. Expected return rate of 80%. Data analysis via multiple regression methodology.

EXPECTED PRODUCTS (MILESTONES): Pilot study - may lead to further studies.

STATUS/RESULTS TO DATE: Sample selected and results coming in. Execution has been complicated by multiple change of address situations. Subjects are being pursued, and where necessary, replacement subjects are selected. Thus far, 104 completed responses have been received.

PUBLICATIONS none to date

Title Musculoskeletal Symptoms in Gulf War Syndrome**Research Focus:** Miscellaneous**Research Type:** Clinical Epidemiology Research**Agency** VA**Study Location** VAMC Long Beach**Study Start Date** 1/1/94**Estimated Completion Date** 1/1/99**Project Status** Ongoing

VA-40

Summary

OVERALL PROJECT OBJECTIVE: The Gulf War Syndrome is most likely a heterogeneous group of disorders resulting from the interaction of each veteran's host defense against the variety of environmental, viral, bacterial and stress toxins unique to the Persian Gulf War. One of the more debilitating symptoms of the GWS has been the arthralgia and arthritis. These complaints are relatively common to foreign deployments. A question arises as to whether musculoskeletal complaints are indeed a manifestation unique to Gulf War Syndrome. The project will address a fundamental question about the Gulf War Syndrome: Do the musculoskeletal symptoms in the GWS reflect those of long foreign deployment or are there unique aspects of these symptoms that identify these symptoms as part of Gulf War Syndrome.

SPECIFIC AIMS: 1. Survey deployments for musculoskeletal symptoms via questionnaire; 2. Compare comparative peace-time vs. Gulf War deployments for musculoskeletal symptoms; 3. Analyze arthritis/arthralgia with comprehensive physical and laboratory examinations.

METHODOLOGY: Veterans of the Persian Gulf War with and without symptoms of the Gulf War Syndrome and healthy veterans of the same period who did not serve in the Persian Gulf but have been deployed for peaceful missions will receive a questionnaire which, if positive, will be followed by comprehensive musculoskeletal evaluation in the Department of Veterans Affairs Medical Center, Long Beach (VAMCLB) and March Air Force Base, California. Statistical analysis of the comparative features of those examinations will be evaluated for appearance of features that could be related to the other than foreign deployment, i.e., GWS.

EXPECTED PRODUCTS (MILESTONES): 1. Survey and range of musculoskeletal symptoms secondary to foreign deployments; 2. Comparison of symptoms between foreign deployments and those to GW theater; 3. Statistical analysis based on chi square and regression analysis of independent variables. Physical and laboratory examination data of deployed reservists/veterans with persistent arthritis/arthralgia complaints from GWS.

STATUS/RESULTS TO DATE: 200+ initial questionnaires; 25 comprehensive examinations. Statistical analysis ongoing.

PUBLICATIONS none to date

Title Diarrhea in Persian Gulf Veterans: An Irritable Bowel-Like Disorder

Research Focus: Miscellaneous

Research Type: Epidemiology Research

Agency VA

Study Location VAMC Gainesville

Study Start Date 11/1/95

Estimated Completion Date 6/30/96

Project Status Ongoing

VA-46

Summary

OVERALL PROJECT OBJECTIVE: To compare visceral sensation in normal subjects, patients with irritable bowel syndrome and patients with diarrhea that abruptly began while serving in the Persian Gulf.

SPECIFIC AIMS: a) To determine if Persian Gulf veterans with abdominal pain, diarrhea and bloating with a negative investigative work-up have an underlying visceral hypersensitivity or a generalized decreased pain threshold. b) To examine the heightened visceral sensitivity present in patients with irritable bowel syndrome and compare the data to those obtained for Persian Gulf veterans with diarrhea. c) To investigate whether an acute treatment with octreotide will increase the tolerance to balloon distention of the rectum and extremity immersion in ice water in Persian Gulf veterans, patients, with the irritable bowel syndrome, and controls. d) To determine the effect of octreotide on oral-cecal transit as measured by the lactulose hydrogen breath test.

METHODOLOGY: Study Design: Informed consent is being obtained prior to the start of the trial. A complete medical history and physical exam will be performed. Blood samples will be collected for a pregnancy test when appropriate. Participants will be asked to discontinue all medications for at least 24 hours before the study, to fast for 12 hours, and to take a Fleet's enema 2 hours before the test procedure. Both the ice water tolerance test and the balloon distention tolerance test will be performed in controls, patients with irritable bowel syndrome, and in Persian Gulf veterans both at baseline and after the administration of octreotide 100 mg subcutaneously. Oral-cecal Transit: The effect of octreotide on small bowel transit will be assessed by the hydrogen breath test. Lactulose (10 g) will serve as the carbohydrate substrate for the breath test. Breath hydrogen concentration is measured by gas chromatography every 15 minutes until peak hydrogen excretion occurs. Peak hydrogen excretion is defined as the highest hydrogen concentration before two successive lower concentrations. Peak hydrogen excretion is the point in time at which the lactulose substrate has reached the cecum. Two points on the hydrogen curve will be used to calculate small intestinal transit. The first is the time to an initial sustained increase of hydrogen concentration of ≥ 10 ppm over baseline. The second point is the time to peak hydrogen excretion. Ice Water Tolerance: The ice water tolerance test is performed to determine if patients have a generalized nonspecific lowered pain threshold from a central pathway. All subjects will be asked to insert their right hand into a mixture of ice and water to the wrist point and to hold it there for as long as possible. The time before withdrawing the hand from the water will be measured with a stop watch for each subject. If the hand is not withdrawn before 4 min, the subject will be instructed to withdraw the hand and a value of 240s will be assigned. Balloon Distention Tolerance: The balloon distention test evaluates a specific visceral afferent pathway as a cause of symptoms in patients with diarrhea. After each subject withdraws their hand from the ice water, a 5-min recovery period is observed. A standard anorectal manometry catheter or barostat (modified manometry balloon that measures rectal compliance) will then be inserted into the rectum of a depth of 10-15 cm. In normal subjects, progressive rectal distention initially leads to the perception of pressure, followed by fecal urgency, and then pain. The subjects' response to progressive rectal distention will be quantitated as: 1) first rectal sensation of the balloon, 2) urge to defecate from balloon distention, 3) rectal discomfort from balloon distention and, 4) rectal pain from balloon distention. The rectal balloon will then be distended in a stepwise fashion by adding 20 ml of air every 3 minutes. Unless this represents the subject's maximum tolerable volume, additional 20-ml increments of air will be added at 3-min intervals up to a maximum of 300 ml. The maximum tolerable volume will be defined as the volume at which the subject requests termination of the

procedure because of discomfort. If the subject does not report discomfort, a value of 200 ml will be assigned. After baseline measurements of ice water and balloon distention tolerance, all subjects are being brought back another day for octreotide testing. Octreotide 100 mg will be subcutaneously administered. Thirty minutes following the injection, the ice water and balloon distention tolerance will be repeated in exactly the same manner as above and compared to baseline values.

EXPECTED PRODUCTS (MILESTONES): Expected results are that the patients with Persian Gulf diarrhea, as well as irritable bowel syndrome, will have similar rectal sensation, as well as similar rectal urge to defecate, as well as similar discomfort relative to distention. Second, it is not expected that there should be a difference in ice water tolerance among either of the three groups.

STATUS/RESULTS TO DATE: At this time, 18 patients have been studied (4 normals, 5 irritable bowel syndrome patients, and 9 patients with Persian Gulf diarrhea). Patients who developed chronic diarrhea while in the Persian Gulf have a significantly lower threshold for symptoms of initial rectal sensation and the perception of discomfort with rectal balloon distension. This visceral hypersensitivity in Persian Gulf Veterans is similar to that observed in patients with Irritable Bowel Syndrome. The hydrogen breath test and octreotide protocols have not yet been completed.

PUBLICATIONS none to date

Mr. EVANS. Okay. And you indicated there was a March symposium concerning research, is it?

Dr. GARTHWAITE. Yes, sir.

Mr. EVANS. And where will that be and what dates?

Dr. MURPHY. It's sponsored jointly with the Society on Toxicology. It's going to be in Cincinnati on March 7 and March 8.

Dr. GARTHWAITE. My apologies. Dr. Fran Murphy is Director of our Persian Gulf War Veterans' Program, and Kris Moffitt is the head of our Compensation and Pension Service. So we have them here available as well.

Mr. EVANS. Dr. Murphy, I recently met with you and the Secretary concerning research grant proposals. When is the deadline for those for the next fiscal year?

Dr. MURPHY. Dr. Joseph can correct me if I'm wrong since it's a DOD-broad agency announcement. The first set of proposals is due on February 10, and the second set on March 19.

Mr. EVANS. So we're already past that date at this point?

Dr. MURPHY. For the first set. But the larger amount of money is actually going to be awarded for the amended proposal for a larger group of studies, and so there would be an opportunity for people to submit through the middle of March.

Mr. EVANS. Vet centers have seen, I understand, some 69,000 Gulf War veterans since May of 1991. What has been learned about these veterans in terms of the problems that they're facing?

Dr. GARTHWAITE. Could you repeat the first part of your question? I just didn't—

Mr. EVANS. I understand that some 69,000 Persian Gulf veterans have visited vet centers since May of 1991. What, if anything, have you learned about these veterans?

Dr. GARTHWAITE. I think the efforts with the vet center population has been on treatment more than diagnosis, so that our efforts have been at dealing with any readjustment issues they might have or any stress related PTSD-related issues that they might have.

Mr. EVANS. But you haven't drawn together any of the vet center personnel to talk about Persian Gulf Syndrome and what they were seeing generally? That seems to me to be a—maybe nonscientific—but a good way of getting to the bottom of some of these issues. Dr. Murphy?

Dr. MURPHY. We've coordinated our activities in the Persian Gulf Health programs very closely with Dr. Batres, who directs the readjustment counseling service, and we're well aware of their activities.

Many of their activities are focused on the areas of readjustment counseling and family counseling related to some of the issues of stress and physical symptoms.

Mr. EVANS. All right, thank you.

Let me refer this question to the Department of Defense people here.

Can you comment on a news report last month that the Army will investigate claims by California biochemist Garth Nicholson that illnesses suffered by many Gulf War veterans may have been caused by the difficulty to detect microorganisms and the possibility of these microorganisms being genetically engineered?

Dr. JOSEPH. Let me comment on part of that, and Mr. Rostker may wish to add something.

This is the same discussion we were having earlier about this researcher. Dr. Nicholson is well known to us in the Department of Defense. He proposed some time ago, a year or more ago, a study related to his somewhat novel theories about Persian Gulf illnesses.

He's a very respected researcher, and his theories deserve to be taken seriously. But they are not exactly down the middle of the road.

Because of concerns about whether the laboratory methodology that he was using could, in fact, demonstrate what he claimed to demonstrate, the Army and the CDC arranged with Dr. Nicholson for a way to validate his laboratory procedures. This would be essential before one could know what one would get from his results.

Unfortunately, Dr. Nicholson didn't come to closure with that validation. Things hung in the balance until a second round of claims by Dr. Nicholson about the need for his research to be funded.

At that second round, the Army has agreed to have the National Institutes of Health serve, in essence, as a referee—as the CDC was going to do about his methodology. We've agreed, from the Department of Defense, that if indeed the NIH validates his methodology, we will go ahead and fund his activity.

That's where it stands at the moment. And that should happen in the next month or so.

Dr. ROSTKER. Actually, Congressman Norm Dix was very much involved in the discussions, and we agreed to ask the National Institutes to be an honest broker here. It turns out that the commander at Walter Reed is—had been the commander in the Army hospital in the vicinity of Congressman Dix's district, and he agreed to be a facilitator in this process bringing all parties together.

So all together, we're talking—we believe we have a process that will lead us towards a resolution of the issue and concerns.

Mr. EVANS. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Quinn.

Mr. QUINN. Thank you, Mr. Chairman.

And I'd like to thank all the panelists this afternoon. Ms. Moffet is the new chairman of the benefits committee where we sort of combined a couple. I'm honored to serve. And while I don't have a question, you're not going to need the microphone.

Mr. Filner and I look forward to working with you as we look at Comp and PIN and how it relates to this with all the rest of the service. So we'll be in touch. Thanks for being with us today.

Dr. Garthwaite, you talked in your opening remarks about some initiatives that have been taken on. And previously today, I talked a little bit about communications. I don't know if you were here for that part of it with another panel, but you talked about some teams as it relates in organized networks.

Can you give me a minute or two more? You mentioned eight people in a team, is that correct?

Dr. GARTHWAITE. Sure, sure. They don't currently exist, but we're targeting early March or the first of April, to have these teams in

place. We anticipate they'll deal with issues way beyond Persian Gulf. We're going to start there.

The goal is to—let me just back up slightly. In rethinking the VA and reinventing it, one of the things we've done is to decentralize to the network level, and we've established as a policy these management assessment councils. They're advisory councils to the network directors, and they include all different stakeholders.

They may include some of your staff. They include veterans' service organizations, academic affiliates, and others. We believe there's a possibility and—or a need and likelihood that doing that at the clinical level may also be helpful at the care level.

So we're going to look at the services we deliver. And each of those services will have an evaluation action team. These teams may take on several services themselves, the goal being to have a formalized process where, at a local level most of these things end up getting solved and occurring, there is a process for ongoing dialogue between our caregivers, our responsible management, people right in the front lines, and the veterans themselves.

Mr. QUINN. Thank you. And I think that is critically important. We're going to talk about—Mr. Filner and I are going to talk about some hearings later in the spring and maybe next fall as it relates to comp in general. But the key—my staff doesn't need to be involved in anything more, thanks anyway.

But the veterans need to be represented on those teams not only from here and some of the service organizations, but around the networks, some rank and file veterans. We're going to hear from some later today, this afternoon. That's critically important. And we'll work with you on that.

Thanks for your answer.

Dr. GARTHWAITE. And we thank you.

Mr. QUINN. Dr. Rostker, you have a very difficult job coming up. You've taken on—I don't need to tell you that. You've taken on a big assignment. You mentioned in your testimony that your office has expanded of late, particularly since your new charge, your new assignment.

How has the office expanded? Has your funding increased?

Dr. ROSTKER. Yes, our funding has increased. We have expanded really in two ways. First of all,—

Mr. QUINN. How much money? Excuse me.

Dr. ROSTKER. I'm sorry?

Mr. QUINN. How has the money expanded? Excuse me.

Dr. ROSTKER. We right now have an operating budget of close to \$15 million dollars. And frankly, as I see new opportunities to be responsive to the veterans and extend the inquiry, I have drawing rights so that we have not placed a limit on this except the good service that we can provide to our people.

Mr. QUINN. Well, and frankly, that's where we come into play as well.

Dr. ROSTKER. Yes.

Mr. QUINN. I, for one, want to help you do that.

Dr. ROSTKER. Right.

Mr. QUINN. We can't open end things, but we will be interested to see what—how about bodies; how about people at the—

Dr. ROSTKER. Right. In order to facilitate an expansion as rapidly as I have, I turn to contract organizations who could bring in people who had the requisite skills; both technical skills, but also had the experience of serving in the Gulf. So we have increased by over ten times.

And we have done that not only in the investigative arm, but also in the veterans' outreach program, as well as bringing in other programs like correspondence and our GulfLINK program. These allow us to have one stop shopping and to get on top of the entire response that we need to make.

Mr. QUINN. One last general question, Mr. Chairman, and then I'll finish.

And I'm not sure to whom this should be addressed. Maybe Dr. Joseph. Just to make sure that we're both—everybody's talking to each other, I get back to this communication point that I mentioned earlier.

As you've got participants in some of your clinical evaluations and they leave, or leave active duty, are they involved in the registry we talked about? Are they placed in the registry? Do they become part of that? Are they there already?

I need some help from somebody on the panel that could—

Dr. JOSEPH. I'm not quite sure of your question. Let me try, and then maybe Dr. Murphy can pick it up.

People come into the registry—the registry is a prior step in both systems to the clinical program. Active duty and reserves have access into our clinical evaluation program. Active duty have a continuing access, of course, as do their dependents, to care in that program.

Those who leave active duty would go over into the VA clinical program. I think that's the fairest way to say it, is that right?

Dr. MURPHY. Yes. As Dr. Joseph is aware, his staff and I talk on an almost daily basis. And the Department of Defense transfers medical records from the CCEP to our registry data base.

Mr. QUINN. Is that a—excuse me. Is that a formal process where it's transferred and there's discussion going on and you're satisfied with that?

Dr. MURPHY. Yes.

Mr. QUINN. And Doctor, you're satisfied?

Dr. MURPHY. We have good cooperation.

Dr. JOSEPH. If there's a soft spot in this process, it's not so much with those who leave active duty and go to the VA system, but those who remain in the Reserves. We've got some work to do to assure access to continuous care as opposed to only evaluation.

Dr. ROSTKER. It's not just the care. It's also the issue of disability discharge. And we are very clear on the active duty person. We're very clear on the person who's separated and is a charge of the Department of Veterans Affairs. It's the reservist who has limited access and also who is in a position to have his career terminated because of health reasons.

We have to really make sure we're not letting them drop through the cracks.

Mr. QUINN. I've gone too long already. Thank you all for your responses.

The CHAIRMAN. Mr. Filner.

Mr. FILNER. Thank you, Mr. Chairman.

Let me just apologize in advance if I may sound skeptical, confrontational, even hostile, because I have been angry on this issue for some time on behalf of my own constituents and people. It does not appear to me that thousands of people who had serious, serious illnesses were either taken seriously by our Government, looked at with any credibility for far too long.

And I'm not convinced that that has changed particularly. So let me—that's my assumption here. And when I—I just had a chance to begin to look at this committee report and heard some of the testimony this morning, and there are statements in there—this is an official Government thing that says the investigations previously were superficial, not credible; there were slow and erratic efforts to release information.

I mean, I don't think it's too far to say "cover up" is a good word for this. And all I can ask—first of all, Dr. Joseph, how long have you been the Assistant Secretary?

Dr. JOSEPH. Since March of 1994. Of course, what you're reading from, Mr. Filner, is not commentary on the clinical evaluation or clinical care efforts. Those—

Mr. FILNER. Well, I'm sure I can find—

Dr. JOSEPH. That same report they said were excellent, as a matter of fact.

Mr. FILNER. Well, who is taking responsibility in DOD for these very serious problems that occurred for the last 4 or 5 years? I mean, has anybody taken responsibility? Are you responsible for any of this?

Dr. JOSEPH. I'm responsible for the health and medical research activities.

Mr. FILNER. Well, are you responsible for the refusal to confront this issue directly for 4 or 5 years?

Dr. JOSEPH. I'm not sure which issue we're referring to.

Mr. FILNER. Well, the issue—we went through Agent Orange in this country where for years and years nobody took seriously that there was anything wrong. And it looked to me—as soon as I heard about these reports of illness, I said oh, they've got to look at it differently.

We have experience that—there's a reality behind here that we've got to figure out, and I didn't see any recognition of that from the DOD or from any official Government source. Everybody tried to say this was not—there was nothing going on here. We didn't do anything, there's no cause, there's no—these people are just stressed or it's in their head.

I didn't see any—I didn't see the institutions taking this seriously.

Dr. JOSEPH. I can speak only for the health and medical research side of it, but I think the evidence is really to the contrary. I mean, we began—and the VA began—very early, a series of programs designed one, to take care of our people; and two, to try to use those efforts to find out what was going on.

Those programs have retrospectively been judged by every group that's looked at them as excellent. Speaking for the Department, not for the VA for the moment, the approach was quite the opposite

from Agent Orange. We started a GulfLINK program declassifying documents and putting them on the Web.

What we've done with our clinical evaluation data base is unprecedented in that we have now made it available to independent scientists who can use it for their own research.

I just do not believe, with all respect, that the facts bear out your comment.

Mr. FILNER. Well, who is responsible for—what is the report referring to when it talks about superficial, unbelievable, slow, erratic, dishonesty? I mean, who are they referring to? Who was the report referring to?

Dr. ROSTKER. The report is characterizing the investigative effort that was in place during the PAC's—

Mr. FILNER. And who is responsible for that?

Dr. ROSTKER. I'm now responsible.

Mr. FILNER. I know. But who was responsible for that?

Dr. JOSEPH. There was no clear line of authority for that. That was the problem.

Mr. FILNER. Mistakes were made.

Dr. JOSEPH. No, mistakes were not made.

Mr. FILNER. Just a quote that I read recently.

Dr. JOSEPH. Yeah, I guess you must have.

Mr. FILNER. The reason I'm even dwelling on this—because I said earlier this morning I'm more interested in getting the care and the benefits done to people who are suffering.

But Dr. Rostker, you sounded—I was very impressed with your statement. And yet, you're put over a bureaucracy that has not performed very well irregardless of what Dr. Joseph just said, in my opinion.

Dr. ROSTKER. And I would not—

Mr. FILNER. And so why do we trust that bureaucracy to help you do what you have to do?

Dr. ROSTKER. I can only say that I don't disagree with you. I found the PAC's characterization consistent with my own inquiry before I was asked to take this particular position. We're trying to put that behind us and look to the future with a program that is responsive.

We're working with veterans. We're working with veterans' service organizations. I can't repair the past by—the only thing I can do is work hard and tell the truth and build to the future.

Mr. FILNER. Well, again, the reason I'm dwelling on this at all is that, as I said earlier this morning, the key national security imperative, in my opinion right now, is honesty. We have not had that.

Why would we get an honest thing now when they've had 4 years of not being honest? We're relying on the same people.

Dr. ROSTKER. Not completely.

Mr. FILNER. Or the same institution, the same dynamics.

Dr. ROSTKER. Not completely, because we have changed the way we are doing business. And I'm able to grab people and work with them in ways that my predecessors just did not do. And the question was raised to the PAC who had the opportunity to look over it, and their conclusion was ineptitude.

And frankly, I would concur with that. I was asked to come in and advise the Deputy Secretary in September, and I had the opportunity to look over the entire institution of what we were doing, how we were doing it. And I wasn't a happy camper.

And when we were getting ready in October to talk to the American people about Khamisiyah, the Deputy Secretary said to me how do I make sure there's no more Khamisiyah's; how do I make sure there's no more surprises?

And I said John, you've got a big problem. The resources the Department has put against this problem were inadequate.

They're totally swamped by the Khamisiyah investigation. They're not being responsive.

For example, we had an 800 hotline where people could come in and report incidences. A very important part of risk communication. We had a thousand phone calls that had not been responded to. Well, I now have in place the resources to respond to it, and, since December 13, we've called, or have been in contact with, almost 700 veterans.

We've called back out of the thousand—we've gone back to that file and made contact with over 300. And by the end of next month, we will have wiped out that back log. That's working towards the future. I've initiated a process of writing what we knew.

Believe me, we knew a lot more than we sat down and wrote. We weren't communicating it with anybody. Well, you will see in the next few days the first case narrative on Khamisiyah, and that's not a final report. It's just an initial report to generate the dialogue so that we can better understand.

We're committed to bringing the veterans into the process. They were the people on the ground in the Gulf. They were the people that have the first hand information. We need to incorporate that.

I can only tell you that I'm running an open process. I welcome public oversight. We have the PAC providing that. We report to congressional committees. I have the PAC at my staff meetings. They're open to talk to anything, to go to any meeting I have. We have absolutely an open process, and we welcome scrutiny to demonstrate that process.

Mr. FILNER. Include me in on your meetings then.

Dr. ROSTKER. Okay, tomorrow at 1 o'clock.

Mr. FILNER. Again, I apologize for the tone. I am——

Dr. ROSTKER. Sir, you have a right to be——

Mr. FILNER. I mean, we have a long way to go to restore credibility of the DOD here.

Dr. ROSTKER. Absolutely.

Mr. FILNER. And I have not heard—I mean, I heard the words. I have not seen all the results yet.

Dr. ROSTKER. And I can only tell you that—you know, stick with us; we're working the problem.

The CHAIRMAN. There will be more hearings, gentlemen.

The gentleman from Louisiana, Mr. Cooksey.

Dr. COOKSEY. I have four questions that—each one of which can be answered with one or two words, so I'll be brief, Mr. Chairman.

First, is the CME on the Gulf War Syndrome available yet? You said it would be available in early 1997.

Dr. GARTHWAITE. The self study?

Dr. COOKSEY. Yes, you said it's going to be made available to the veterans' physicians.

Dr. GARTHWAITE. We can make it available to—and anyone else who's interested.

Dr. COOKSEY. Okay, there are two of us on this panel that are physicians, and—

Dr. MURPHY. It's in the final stages of development, and we'd be happy to provide you a copy.

Dr. COOKSEY. I'd like to get one. It will help me keep up with my CME. It's not easy to do here.

Dr. Joseph, what is the incidence of Gulf War Illness among the men that were involved in destroying those chemicals that were there on the site?

Dr. JOSEPH. If we look at people who were already participants in the clinical program, which is all we can look at yet, both the prevalence and the nature of symptoms and illnesses do not appear different from the overall group in the CCEP.

Now the questionnaire that Bernie was talking about being sent out, has been sent out to all members of units who we judged to have been within a 50 mile radius. We don't have all that data back, and even then it will be self-reported symptoms.

So, I can't really answer your incidence problem. But if we look at comparable incidence or prevalence and patterns of illness or symptoms within the group that had previously registered themselves in the CCEP, it is comparable. There are no significant differences that we can discern.

Dr. COOKSEY. I think that's an important question that needs to be answered because of the Khamisiyah situation.

Dr. JOSEPH. Sure.

Dr. COOKSEY. Dr. Rostker, you have the potential to become the hero of this. I think the thing that really needs to be done instead of finding fault with people is find the reason for it. Because as a physician with scientific training, once we find the cause of it, then we can direct some treatment, and I hope you can do that.

My question: have any studies been done or inquiries been made about—to the Saudis or some of the Arabic forces there, even to the Iraqis, to see if they've had symptoms?

Dr. ROSTKER. There has been some. There was—the Army Surgeon General was in Kuwait. I intend later this spring to take a team to Britain, Czechoslovakia, Israel, and Kuwait and replot that ground. A lot of this ground has been plowed, but it's important that we take a fresh look and we go over this once more.

And we'll be doing that, and we'll have an interagency team going with me.

Dr. COOKSEY. Good.

Thank you, Mr. Chairman.

The CHAIRMAN. The Chair recognizes the gentleman from Georgia, Mr. Bishop.

Mr. BISHOP. Thank you very much.

I look forward to working with Mr. Everett from Alabama, who is going to be the chair of the new subcommittee on oversight and investigations, and I will, of course, be the ranking member—with all of you as we explore this whole phenomenon of the Gulf War Illnesses.

I'm given to understand that a number of Gulf War veterans are of the opinion that some VA doctors and researchers have been subjected to some retaliation for their efforts to really pursue the research and to really get to the bottom of whether or not there is in fact a common thread in these illnesses.

Can—Dr. Garthwaite, can you tell me if any physician has been directed by the VA to cease providing treatment or has any physician been punished, reassigned, or put under a cease and desist order for activities with regard to the research regarding Gulf War illnesses?

And I specifically refer to anyone from the VA hospital in Tuskegee.

Dr. GARTHWAITE. Sir, to my knowledge, we certainly have not attempted to interfere with anyone who's taking care of Gulf War veterans. It is our hope that we can encourage everyone who's interested in doing research to put forward credible studies that can be scientifically reviewed to study Persian Gulf War veterans.

And it's our goal to encourage people to study that. So to my knowledge, no. There have been some things in the press that we're currently looking at, which we don't think are related at all to any activities in the Persian Gulf, but we can provide you additional detail on that.

Mr. BISHOP. There was a physician who was doing some discussion with veterans groups in the Tuskegee area, at least veterans who are served by that particular VA facility. And there was some talk and some media coverage that he had been subjected to some retaliation or to some discipline for statements, comments, or information that was disseminated.

Can you shed any light on that?

Dr. GARTHWAITE. Dr. Murphy may know more about that specific case.

Dr. MURPHY. That was before Dr. Garthwaite joined the central office staff.

I believe you're referring to Dr. Charles Jackson at the Tuskegee VA. And he very early on, back in late 1992, expressed his feeling that some of the Persian Gulf veterans that he had seen might have had illnesses as a result of exposure to chemical and biological warfare agents.

And he named some specific viruses that he felt might be responsible for their illnesses or chemical warfare agents that they may have been exposed to. VA took that very seriously. We sent a team of experts down to evaluate that, including our infectious disease consultant.

And we established a special pilot program at the Birmingham VA where they have special neurologic expertise and neuropsychological expertise to further evaluate and treat those veterans. That program was expanded last year into a fourth Persian Gulf referral center at the Birmingham VA Medical Center.

So VA actually took the concerns of that physician very seriously and responded, I think, in an appropriate way.

Mr. BISHOP. What happened to Mr. Jackson?

Dr. MURPHY. Dr. Jackson is still working at the Tuskegee VA and still caring for Persian Gulf veterans. I had the opportunity to

meet him in the last couple of months when he came up to Washington to testify.

Mr. BISHOP. Was he disciplined or reprimanded for any of his activities?

Dr. MURPHY. No. To my knowledge is that his Chief of Staff at the Tuskegee VA was very supportive. And certainly his comments to us have reflected that.

Dr. GARTHWAITE. We'd be happy to take a further look at any specific information on that case. We'd be happy to. And we'll look into it on our own.

Mr. BISHOP. Thank you very much, but let me just say that this just goes again to underscore the lack of trust, the cynicism, and the lack of confidence that many of the veterans have as a result of this whole fiasco really.

It just has undermined to a great extent the confidence the veterans have in the Government that they have served. And of course, VA, of course, and DOD are the prime agencies that touch their lives. And certainly we want to create as much credibility in those agencies, and we want to make sure that the facts are forthcoming.

And I just want to say that, and I don't have any further questions.

Thank you.

The CHAIRMAN. Thank you, sir. Mr. Stearns.

Mr. STEARNS. Thank you, Mr. Chairman. I hope I don't go back over some things that have already been covered.

But let me ask Dr. Joseph: what is gamma globulin? What is it and how is it used in vaccines in its purpose?

Dr. JOSEPH. Gamma globulin is a naturally occurring product in the body which is part of the body's immune defense against various invading bacteria or viruses. It's not really used in vaccines, but preparations are used to boost or supplant the body's own defenses.

In the days before we had a hepatitis vaccine, we gave troops and civilians gamma globulin when they were going to an area where they might be exposed to hepatitis virus.

Mr. STEARNS. Okay. Isn't it true that our troops were given that before they went over to Desert Storm?

Dr. JOSEPH. Some troops were given gamma globulin. They were given it for the purpose that I have described. And they've been given that for a long time when deploying to lots of places.

Mr. STEARNS. But isn't it true that the DOD used non-FDA approved products, that not all of the products came from American made approved FDA proved products; but in fact, some of these products came from Italy, and these were used on our—

Dr. JOSEPH. You mean gamma globulin that was not FDA approved? I don't know the answer to that. Dr. Nightengale might know. I doubt it very much. I will get back to you on it. I've not heard that before—that particular allegation before.

Mr. STEARNS. Well, you know, I think we—my staff and I have found evidence that in fact the DOD used non-FDA approved products for the troops before they went to Desert Storm. And in fact, some of it came from a company in Italy. And—

Dr. JOSEPH. Well, I'd appreciate that information that you have, and I will certainly run it by both our people and with the FDA.

I think that would be very unusual. Not unusual. I think we would not do that.

Mr. STEARNS. Unusual for the United States to use non-FDA approved, or—because you have the authority, DOD, for exceptions. You can go outside the United States.

Dr. JOSEPH. Yes.

Mr. STEARNS. That's true.

Dr. JOSEPH. Yes.

Mr. STEARNS. Have you researched that fact? In fact, the DOD went outside the United States, used a product from Italy, and it was not FDA approved. Did you know that?

Dr. JOSEPH. That's the first time I've heard that. We'll certainly look at it. The allegation one usually hears about non-FDA approval has to do with the pyridostigmine bromide. And that's an instance where we, again, had an exception from the FDA to use an approved product for a non-approved use.

Mr. STEARNS. Who is the American made company that provided the gamma globulin?

Dr. JOSEPH. I can't tell you that sitting here. We can find out.

Mr. STEARNS. Okay.

Dr. JOSEPH. I assume this is back in 1990.

Mr. STEARNS. When a veterans comes in and complains, the tests that he or she are given, do they check for hepatitis C? If you have absolute proof that every veteran that came in with Gulf War Syndrome, do you check for hepatitis C or—

Dr. JOSEPH. We do not, nor would the VA, check each and every veteran who "came in" for hepatitis C. The way the clinical evaluation programs work is a ladder-like series of exams that follow symptoms and—

Mr. STEARNS. Well, did you give them a blood test?

Dr. JOSEPH. Yes.

Mr. STEARNS. You gave them a blood test?

Dr. JOSEPH. Well, for many things and for different things. But the simple answer to your question is no, neither in the VA system nor in the DOD program was every—

Mr. STEARNS. Did you keep samples of that blood? Once you gave that blood test, do you have records of that blood in file anywhere?

Dr. JOSEPH. We would have serum samples on all our active duty people, not only those who came into the CCEP.

Mr. STEARNS. So if I came in and I complained of Gulf War Syndrome, you took my blood, I could be assured that that blood is on file—is kept, or is it thrown away?

Dr. JOSEPH. You can be sure that we have a serum specimen on you.

Mr. STEARNS. And do you know, when they do those blood tests, is there various biological contaminants and retroviruses and neurotropic viruses and paroviruses? I mean, is it possible that what we're talking about here is something that was given to the veteran perhaps through another country that's not FDA approved, and that veteran is experiencing some kind of problem—hepatitis A, B, C, D, who knows—and one we haven't checked for, we haven't kept a record of it, and we haven't gone back to the source to check the product that was given to us that was not FDA approved?

Dr. JOSEPH. I think the chain of logic that you're describing is extremely implausible. But, I can't say that it's not so, especially since I don't know what the answer to your first question is. And I will find out.

Mr. STEARNS. Okay. Well, I think—you know, that's the basic question. Because if that's true, then that's another tack that I don't think everybody has perhaps thought about that we could think about and followed along that line.

Dr. JOSEPH. If I may, as sort of a tangential answer to that: if what you say is so, it is not impossible that there may be some small group of veterans who have a particular condition that might—although I think it's highly improbable—be related to that.

But, what I think everyone who has looked at this issue seriously has found, and every study that's been done on the clinical side, and the reviews of those studies has found, is that there is no single one unique overriding cause of these symptoms and illnesses.

So that even if what you're positing is possible or true, and it may be, it would explain only a small group of people—if indeed it were true—rather than an overriding cause. But we will look at that. It's a completely new one to me. I thought I had heard them all.

Dr. GARTHWAITE. I was just going to say, as the phase one of our examination process, everyone received liver function tests, and all those that were positive would have gone on to the phase two to get hepatitis screening or the phase two part of the examination.

So we would assume that if they were infected with hepatitis C, which there probably wasn't a good test at the time, then we would have picked up—at the active time of the illness some liver function abnormalities to get us onto that diagnosis.

Mr. STEARNS. If you did the test.

Thank you, Mr. Chairman.

The CHAIRMAN. The gentleman from Arkansas, Dr. Snyder, is recognized.

Mr. SNYDER. Thank you, Mr. Chairman. Just for time's sakes, if I could just direct my questions to Dr. Jackson.

Is it a fair statement to say to this table if we all have you back in a year or 2 years or 3 years that kind of all funded research, you all are going to know about it, what's coming through Government and be able to tell us what's going on—is that an accurate statement?

Is this kind of the research gurus here in terms of the administrative part of it at least?

Dr. JOSEPH. Some answers won't be in in 3 years.

Mr. SNYDER. I meant in terms of what are the status of things.

Dr. JOSEPH. Yes.

Mr. SNYDER. I'm not asking for—I don't—and then there has been a view expressed perhaps as we're hearing more and more folks say, you know, we're not getting all the answers, there's no one cause, and maybe we ought to forget the whole research thing and just put all the money into seeing folks at the—are you all in agreement that that's the wrong approach?

I want to see if you all change your head from shaking.
[Laughter.]

Dr. JOSEPH. It's the wrong approach. CDC funded this study in Iowa, for example. We've captured a population of veterans. We've looked at the prevalence of illness in that population. These are not people that came through and said I have a problem.

These are people that were going about their lives. They have higher rates of cognitive dysfunction, depression, anxiety, asthma, bronchitis, a number of other symptoms. So, following that population, they report those higher rates of illness.

The next step is to go back and examine a group of them randomly selected. I think one of the problems has been the need to look at a profile of the population rather than only looking at people who come to you saying they have a problem.

Mr. SNYDER. I assume that behind all this talk of research I'm in agreement on is to perhaps avoid problems in the future. I mean——

Dr. ROSTKER. That's exactly right. If we can't get to the bottom of this, how will we protect our troops in the future?

Dr. JOSEPH. Well, the problem is, what's the bottom. That's the problem.

Mr. SNYDER. I'm sorry, sir?

Dr. JOSEPH. The problem is, what's the bottom. I think I can tell you with absolute surety that there are some questions in this morass that will never be answered. There are some questions that will be answered.

Mr. SNYDER. That may help shape future behavior.

Dr. JOSEPH. That's right. The PAC representative, this morning in the other hearing, said that it is becoming increasingly unlikely that one, there will be a connection between a Gulf War Syndrome and the sort of commonly thrown about possible causes; and, two, that there will be any persuasive evidence that there is a Gulf War Syndrome.

Mr. SNYDER. And it's the folks—go ahead. I'm sorry.

Dr. ROSTKER. If I might. I may be the only non-physician on the panel, and so my bottom line is not just the health bottom line, but is a whole myriad of things that are necessary to protect our troops in the future from better chemical alarms, better reporting procedures, knowledge of where our troops were.

So there are a lot of lessons to be learned here, as well as the medical lessons to understand why people are sick.

Mr. SNYDER. You referred to the morass. My last question is—I mean, when is enough enough? I mean, do we even have a sense yet of—are we talking, you know, a money pit here that's going to go on 20 years from now?

We'll be talking about additional research on Gulf War Syndrome with big amounts of money, or are we—do you all have some thought in your mind that we just need another, you know, 2 or 3 or 4 years of pretty good funding to kind of—I mean, I assume that you all talk amongst yourselves about how long we're going to be doing this or need to do this.

Dr. JOSEPH. I think there is important ground to be plowed. On the medical research side there is important ground to be plowed on the Research regarding combination of agents, particularly with pyridostigmine. There is important ground to be plowed on the population-based epidemiology studies.

And there is important ground to be plowed on the issues of the relationship between stress and psychological issues and physical symptoms and illnesses. In those three areas we have not begun really to get to the bottom.

Mr. SNYDER. I guess this is really my last question. Do any of you anticipate that perhaps out of some of that there will be a shift in treatment of some of the Gulf War veterans? I mean, is there some hope for that, or do we think we're just going to understand what happened?

Dr. JOSEPH. Personal, professional opinion: no, that there will not be—there's not a magic bullet here. There's not a shift in treatment. We will not discover a thing that leads to a major difference in treatment.

Mr. SNYDER. But you'll be able to call up veterans and say we've got the answer for you; come on in, take a pill?

Dr. JOSEPH. I don't believe that's going to happen, sir.

Mr. SNYDER. Thank you, Mr. Chairman.

Dr. GARTHWAITE. I think what does occasionally happen is that as we take care of patients, we find things that are more or less clinically effective; and, there were drugs for depression that were very helpful in peripheral neuropathy in diabetics.

So there may be further discoveries that very much help with symptomatic therapy.

The CHAIRMAN. The gentlelady from Idaho, Ms. Chenoweth, is recognized.

Mrs. CHENOWETH. Thank you, Mr. Chairman.

Dr. Garthwaite, I wanted to ask you why the VA is proposing to cut research funding by 10 percent at a time when the President's Advisory Commission is calling for more research, and the President himself has stated that no stone should be left unturned?

Can you tell me that?

Dr. GARTHWAITE. I think that the Department's been faced with some very difficult decisions over the past few months as we've begun to put forward the budget for next year. We've been caught up in the debate over balancing the budget when we were—when there was a Government shut down.

And we really do understand the budget pressures. We are trying to put forward a very creative and aggressive budget for us into the future. So tough choices were made. We do believe that as we go through our prioritization process, we can keep at the forefront the needs of veterans.

In addition, we're challenging our investigators to go outside the VA to bring in dollars. One of our new performance measures for our network directors and for our networks will be to increase the number of total dollars brought in to the VA for research so that we're going to add some additional pressures to compete with NIH and other funding agencies for research.

Mrs. CHENOWETH. Doctor, I assume that you—when you talked about your priorities, that Gulf War Syndrome would be on the top of your list of priorities.

Dr. GARTHWAITE. It's in the first tier.

Mrs. CHENOWETH. Thank you.

Dr. GARTHWAITE. Yes, ma'am.

Mrs. CHENOWETH. It just seemed a little inconsistent, the 10 percent cut. But I look forward to working with the Department of Veterans Affairs on this.

You know, it may seem a little bit picayune when one questions citations, but we have to admit that when a veteran would receive long sought after medical records with the stamp on the bottom that I read in my last questioning section about a \$20,000 fine if any of these records should be released to any military personnel handling the records, they would be prone not to ship records out.

And I did some research yesterday and my staff did too, and then counsel here on the committee has been working with me the last few minutes. Because the cite that is used, 38 USC 33.05, doesn't exist at all. And counsel actually referred me to the quality assurance section that does cite a potential of \$20,000 fine.

But quality assurance, QA/QC, is not medical records of a patient. In the code, it states that for the first offense, there should not be a fine of more than \$5,000. And it—the fine could go up to \$20,000 on subsequent violations of a breach of the confidentiality of a quality assurance program.

The confidentiality of medical records is elsewhere in the code, in 7332; and QA/QC is in 5705. Now, if we're confused about that here, can you imagine how a veteran feels when he gets this on his records?

Mr. Chairman, with your permission, I would like to have Dr. Garthwaite take a look at this. Because my concern is how—although I'm so impressed with the testimony that you gentlemen and ladies have given, nevertheless, we need to get to where the rubber meets the road and what's happening to these veterans out there that are affected with symptoms that could be Gulf War Syndrome.

And so it just seemed a little heavy handed, and I'm not going to publicly enter into the record the name of the hospital, but I know that you will take care of that for us——

Dr. GARTHWAITE. Sure.

Mrs. CHENOWETH (continuing). And straighten it out.

[The information follows:]

**Department of
Veterans Affairs**

Memorandum

Date **FEB 27 1997**
 From General Counsel (024)
 Subject Congressional Inquiry on Improper Use of Quality Assurance
 Confidentiality Provision
 To Assistant Secretary for Public and Intergovernmental Affairs
 (002)

1. You recently requested that we look into a complaint from the Office of Congresswoman Helen Chenoweth regarding the use of the VA quality assurance records confidentiality provision to limit veteran David T. Smith's use of his own medical care and treatment records. The matter arose at the VAMC Walla Walla, Washington. As this was a VHA issue, we asked the VHA Privacy Act officer, Celia Winter, to inquire into the case. We received the attached station documents from Ms. Winter.

2. The station documents reflect that when they provided Mr. Smith with a copy of his records pursuant to his request they improperly applied their quality assurance confidentiality warning stamp to the records. The stamp indicates that the records cannot generally be disclosed and identifies a penalty for unauthorized disclosure. It appears that the veteran contacted a newspaper reporter, complaining of this apparent limitation. From the VAMC documents, and from Central Office staff contacts with this office, it further appears that in December, 1996, the reporter contacted various VA offices in the field and in Central Office, including Public Affairs. His inquiries lead to the VAMC being advised that affixing this warning on care and treatment records was an error. The VAMC then told the patient to disregard the stamp and has taken steps to prevent recurrence of such an event. An imprint of the stamp is contained in the VAMC documents.

3. The quality assurance provision stamp is authorized to be used on protected quality assurance documents only; those records basically are peer review assessments of the care provided at a facility. While patient records are protected under a number of confidentiality provisions, the quality assurance provision generally does not apply to those types of records. This provision originally was section 3305 of Title 38, U.S.Code but it was renumbered in 1991 and is now section 5705.

4. Additionally, the Regional Counsel has explained the proper use of the quality assurance provision to personnel at that facility and has scheduled a training class on Information Law

2.

Assistant Secretary for Public and Intergovernmental Affairs (002)

for March. The station has not yet replaced the stamp which they were using; however, they know that their stamp is out-of-date. A copy of the quality assurance records confidentiality law, and implementing regulations, is attached.

5. It is our understanding that Doug Dembling, of the Congressional Affairs staff, is our contact point for providing a reply to the Congresswoman. Accordingly, we are making a copy of this memo, and the attachments, available to him for that purpose. If further information is needed in this matter, Jeff Corzatt, telephone number 273-6362, is familiar with the case.

Mary Lou Keener

Attachments

cc: Doug Dembling (60) ✓
w/attachments



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
77 Wainwright Drive
Walla Walla WA 99362

12/19/96

In Reply Refer To:

REPORT OF CONTACT

1. We have learned that Mr. Norm Brewer, reporter for Gannett News Service, contacted VA Central Office (Public Affairs) in followup to an issue involving veteran David T. Smith. A previous report of contact regarding Mr. Smith was sent to you on December 18, 1996.
2. Mr. Brewer is questioning a stamp that appeared on a cover letter from this VA Medical Center to Mr. Smith on December 3, 1996 accompanying copies of the veteran's medical record. These records were released to Mr. Smith himself based on a request we received from him. We have now learned from Regional Counsel that the reference to 38 U.S.C. 3305 is outdated, since it was renumbered to 38 U.S.C. 5705 in 1992. Further, the stamp itself should not have been used for release of a veteran's medical record to himself but rather the stamp would have been appropriate for release of quality assurance records.
3. We have advised Mr. Brewer of the above and have instituted corrective action to prevent this from recurring. We have also contacted Mr. Smith and told him to disregard the stamp. A copy of the stamp used on the letter to Mr. Smith is shown below.


George Marnell
Medical Center Director

"These documents or records (or information contained herein) are deemed confidential and privileged under provisions of 38 U.S.C. 3305 and VA Regulations 6500 through 6540, which provides for fines up to \$20,000 for violations. This material shall not be transmitted to anyone without proper consent or other authorization as provided for by law or regulation."



DEPARTMENT OF VETERANS AFFAIRS
 Medical Center
 77 Wainwright Drive
 Walla Walla WA 99362

Report of Contact

In Reply Refer To:

Person Contacted: Mr. Norm Brewer
 Reporter, Gannett News Service
 Washington, D.C.

Phone: 703-276-5832

Date: 12-17, 18-1996

Subject: Veteran David Troy Smith (519-94-8549)

1. The Gannett News Service, which contracts to provide news articles to an array of newspapers, including U.S.A. Today, called on December 17, 1996, at approximately 3:30 PM about the above designated veteran. The reporter, Mr. Brewer, had the following concerns:

a. He stated that on December 1, 1994, veteran David Troy Smith had been diagnosed at the West Los Angeles VA Medical Center with irritable bowel syndrome, gastroesophageal reflux disease, hepatomegaly and several other diseases.

b. According to David Smith (as related to the Gannett reporter), he had been prescribed morphine at the West L.A. VAMC; however, when he ran out of the drug and attempted to have it refilled here, he was denied access to it. Mr. Brewer wanted to know why the Walla Walla VAMC denied him a refill of his morphine prescription, and whether or not there was a breakdown in communication between the two facilities. (Caveat: His record does not confirm that he was prescribed morphine at the West Los Angeles VAMC; however, he was prescribed both dilaudid and percocet.)

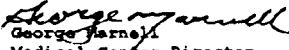
2. The Chief of Staff reviewed David Smith's chart, and could well understand the veteran's concern about his health. This patient is a veteran of the Gulf War, who denies smoking, drugs and alcohol consumption. He complains of general fatigue and had several bouts of diarrhea and abdominal cramps which began while serving in the Persian Gulf, which have persisted. He suffers from arthralgias in all joints and chronic low back pain. This is accompanied by muscle stiffness and cramping. He reports a short term memory loss. He had lost 50 pounds during the month prior to his admission on October 26, 1994. He reportedly has had a

traumatic brain injury in the past, but could not provide specifics. The record also indicates that he has hypertension and PTSD.

3. Mr. Smith is a sporadic user of our services, and lives 100 miles from our facility. He failed to keep his last scheduled appointment on December 12, 1996. Our plan is to contact him, and invite him to the medical center for re-evaluation and/or follow-up care.

4. On December 18, 1996, following conversation with the Acting Director, Los Angeles Office of Public Affairs, a call was made to Mr. Brewer by the Walla Walla VAMC Chief, Community Resources Service. He instructed Mr Brewer that while we would be pleased to provide him information regarding care to Gulf War Veterans generally, that it was not in the best interest of Mr. Smith to discuss the details of his medical condition.

5 Mr. Brewer then asked if, off the record, there was anything additional to share with him. He was given a negative reply.


George Barnard
Medical Center Director

§ 5705. Confidentiality of medical quality-assurance records

(a) Records and documents created by the Department as part of a medical quality-assurance program (other than reports submitted pursuant to section 7311(g) of this title) are confidential and privileged and may not be disclosed to any person or entity except as provided in subsection (b) of this section.

(Added P.L. 96-385, § 505(a); amended P.L. 99-166, § 201; P.L. 102-40, §§ 402(b)(1), 403(b)(2); P.L. 102-83, § 4(a).)

(b)(1) Subject to paragraph (2) of this subsection, a record or document described in subsection (a) of this section shall, upon request, be disclosed as follows:

(A) To a Federal agency or private organization, if such record or document is needed by such agency or organization to perform licensing or accreditation functions related to Department health-care facilities or to perform monitoring, required by statute, of Department health-care facilities.

(B) To a Federal executive agency or provider of health-care services, if such record or document is required by such agency or provider for participation by the Department in a health-care program with such agency or provider.

(C) To a criminal or civil law enforcement governmental agency or instrumentality charged under applicable law with the protection of the public health or safety, if a qualified representative of such agency or instrumentality makes a written request that such record or document be provided for a purpose authorized by law.

(D) To health-care personnel, to the extent necessary to meet a medical emergency affecting the health or safety of any individual.

(2) The name of and other identifying information regarding any individual patient or employee of the Department, or any other individual associated with the Department for purposes of a medical quality-assurance program, contained in a record or document described in subsection (a) of this section shall be deleted from any record or document before any disclosure made under this subsection if disclosure of such name and identifying information would constitute a clearly unwarranted invasion of personal privacy.

(3) No person or entity to whom a record or document has been disclosed under this subsection shall make further disclosure of such record or document except for a purpose provided in this subsection.

(4) Nothing in this section shall be construed as authority to withhold any record or document from a committee of either House of Congress or any joint committee of Congress, if such record or document pertains to any matter within the jurisdiction of such committee or joint committee.

(5) Nothing in this section shall be construed as limiting the use of records and documents described in subsection (a) of this section within the Department (including contractors and consultants of the Department).

(6) Nothing in this section shall be construed as authorizing or requiring withholding from any person or entity the disclosure of

statistical information regarding Department health-care programs (including such information as aggregate morbidity and mortality rates associated with specific activities at individual Department health-care facilities) that does not implicitly or explicitly identify individual patients or employees of the Department, or individuals who participated in the conduct of a medical quality-assurance review.

(Added P.L. 96-385, § 505(a); amended P.L. 99-166, § 201; P.L. 102-40, § 402(b)(1); P.L. 102-83, § 4(a).)

(c) For the purpose of this section, the term "medical quality-assurance program" means—

(1) with respect to any activity carried out before October 7, 1980, a Department systematic health-care review activity carried out by or for the Department for the purpose of improving the quality of medical care or improving the utilization of health-care resources in Department health-care facilities; and

(2) with respect to any activity carried out on or after October 7, 1980, a Department systematic health-care review activity designated by the Secretary to be carried out by or for the Department for either such purpose.

(Added P.L. 96-385, § 505(a); amended P.L. 102-40, § 402(b)(1); P.L. 102-54, § 14(d)(4); P.L. 102-83, § 4(a), (b).)

(d)(1) The Secretary shall prescribe regulations to carry out this section. In prescribing such regulations, the Secretary shall specify those activities carried out before October 7, 1980, which the Secretary determines meet the definition of medical quality-assurance program in subsection (c)(1) of this section and those activities which the Secretary has designated under subsection (c)(2) of this section. The Secretary shall, to the extent appropriate, incorporate into such regulations the provisions of the administrative guidelines and procedures governing such programs in existence on October 7, 1980.

(2) An activity may not be considered as having been designated as a medical quality-assurance program for the purposes of subsection (c)(2) of this section unless the designation has been specified in such regulations.

(Added P.L. 96-385, § 505(a); amended P.L. 102-40, § 402(b)(1); P.L. 102-54, § 14(d)(4); P.L. 102-83, § 4(b).)

(e) Any person who, knowing that a document or record is a document or record described in subsection (a) of this section, willfully discloses such record or document except as provided for in subsection (b) of this section shall be fined not more than \$5,000 in the case of a first offense and not more than \$20,000 in the case of a subsequent offense.

(Added P.L. 96-385, § 505(a); amended P.L. 102-40, § 402(b)(1).)

SUBCHAPTER II—INVESTIGATIONS

§ 5711. Authority to issue subpoenas

(a) For the purposes of the laws administered by the Secretary, the Secretary, and those employees to whom the Secretary may

of Federal Regulations, is amended as follows:

PART 165—(AMENDED)

1. The authority citation for Part 165 continues to read as follows:

Authority: 38 U.S.C. 1231; 38 U.S.C. 191; 33 CFR 1.65–4(g), 6.04–1, 6.04–6, and 190.1; 48 CFR 1.46.

2. In section 165.702–004 paragraph (b) is revised to read as follows:

§ 165.702–004 Safety Zone: Upper Mississippi River mile 42.0 to 43.7.

(b) *Effective date.* This section is effective from August 24, 1994 and terminates on December 24, 1994.

Dated: October 17, 1994.

Robert M. Segowitz,

Commander, U.S. Coast Guard, Captain of the Port, Paducah, Kentucky.

[FR Doc. 94–26312 Filed 10–21–94; 9:45 am; Sales Code 999–999–999]

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2990–AD01

Confidentiality of Healthcare Quality Assurance Reviews

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations which govern the confidentiality of documents produced in VA healthcare quality assurance programs. These regulations specify and provide for the limited disclosure of those quality assurance documents which are confidential under the provisions of the Dept. of Veterans Affairs Confidentiality of Medical Quality Assurance Records Act of 1980, 38 U.S.C. 5705.

EFFECTIVE DATE: This amendment is effective January 23, 1995.

FOR FURTHER INFORMATION CONTACT: Carol L. Barbour, M.D., Associate CMD for Quality Management (15), 816 Vermont Avenue N.W., Washington, D.C. 20420.

SUPPLEMENTARY INFORMATION: VA published a proposal to amend 38 CFR part 17 in the Federal Register of August 20, 1993 (58 FR 44318).

Interested persons were invited to submit written comments, suggestions or objections on or before September 20, 1993. We received one comment from the American Psychiatric Association.

The commenter noted that the standards for disclosure of medical quality assurance records protected by section 5705 do not mirror the standards recently proposed by the VA regarding the confidentiality of patient records related to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus (HIV) and sickle cell anemia. The commenter asked that VA articulate any statutory or public policy differences regarding the protection of these two categories of records.

Each category of records is protected by a statute which specifically provides that records subject to it may be released outside the agency only as authorized by that particular statute of title 38. Section 5705 applies to medical quality assurance records, and section 7332 applies to drug abuse, alcoholism or alcohol abuse, HIV infection and sickle cell anemia. The VA regulations in each case reflect the protection and the disclosure authority specified by Congress in each statute.

This revision of the regulations in 38 CFR part 17 applies to healthcare quality assurance records and documents created after the date on which the revision becomes effective.

The previous regulations are still applicable to records and documents created prior to that date and remain protected by 38 U.S.C. 5705 (formerly 38 U.S.C. 5905), Confidentiality of Medical Quality Assurance Records. Records generated for reviews which are initiated prior to the effective date of this revision and are in accordance with the previous regulations are protected by the previous regulations even if the records are completed after the effective date of this revision.

This revision is necessary to update the previous regulations which were published in 1982. Much of the language in those regulations no longer reflects the practice and terminology of quality assurance.

These revised regulations describe the conditions determining the confidentiality of documents produced in quality assurance programs.

They do not specify the quality assurance program requirements for VA medical facilities; the rapidly changing environment to which quality assurance programs respond requires that policy guidance on this subject be presented in a more flexible and readily modifiable format. Consequently, the Veterans Health Administration (VHA) is simultaneously publishing a directive delineating the specific quality assurance requirements for VA medical facilities and the oversight

responsibilities of VHA regarding these requirements.

To be confidential and privileged under 38 U.S.C. 5705 and these regulations, a document or part of a document must meet all four of the following criteria:

1. The quality assurance activity which generated the document must fall under one of the four classes listed in 17.501(a).

2. In accordance with 17.501(b), the activity which generated the document must have been previously designated in writing as an activity which produces confidential quality assurance documents.

3. The document or part of document must meet one of the five conditions described in 17.501(c).

4. The document or part of document must not meet any of the conditions in 17.501(d).

The revised regulations allow confidential information concerning a provider to be seen by that provider for educational and quality improvement purposes. To protect the integrity of the peer review process, the identities of the peer reviewers involved in the creation of the data will not be disclosed to the provider, to the extent practicable. We believe these changes will permit a flow of information conducive to continuous quality improvement by making information on their practice readily available to clinicians.

Information concerning the number of cases treated and procedures performed by individual providers will no longer be confidential and protected by 38 U.S.C. 5705 and these regulations. Consequently, 38 U.S.C. 5705 no longer constitutes a bar to VA facilities placing this information in a practitioner's credentialing and privileging folder. Since this information is important to the evaluation of a practitioner's request for renewal of clinical privileges, making it more readily available should increase the effectiveness of that process.

The specific examples of programs and activities cited in 17.501(a) are included to provide guidance to VA facilities in classifying their review documents to simplify coverage under these regulations. Documents from other systematic healthcare quality assurance reviews which meet the criteria in 17.501 are also confidential.

It is expected that VA facilities will indicate on all confidential review documents created after the publication of these regulations that the document is confidential under 38 U.S.C. 5705 and these regulations and also will designate the specific program or activity within which the review is included. The

program and activity names used should be from the policy documents referred to in 17.501(b). However, it is not necessary for the facility to have taken these steps for a document which meets the criteria in 17.501 to be confidential and privileged.

These regulations recognize that there are two types of external reviews of care conducted by VA Central Office and the Regions. One type generates documents which are made confidential and privileged by 38 U.S.C. 5705 while the documents resulting from the second type of external review are not protected by that statute. Sections 17.501(a)(2), 17.501(a)(3) and 17.501(g)(9) clarify existing agency procedures in this respect.

This revision does not address the filing of confidential quality assurance documents by individual identifiers. This change from the previous regulations does not mean that it is now legal to file documents in this manner. Guidelines will be provided to the field when this issue is resolved.

The revised regulations no longer specify the manner in which VA facilities will maintain and protect records containing information protected by 38 U.S.C. 5705. However, all VA facilities are expected to provide the level of protection reasonably necessary to ensure that access to and disclosure of all records containing information protected by 38 U.S.C. 5705 will occur only as authorized by the statute and implementing regulations.

Under these regulations, quality assurance investigations may be initiated as needed by facilities as focused reviews. Focused reviews can be used to study both specific incidents and specific issues. Records and documents relating to focused reviews will be confidential and privileged if they meet the criteria in 17.501.

As in the past, information and records derived from patient medical records or facility administrative records, which are not protected by 38 U.S.C. 5705 and these regulations, may be sent or communicated to a third party payor who has asked for this information in response to a VA request for reimbursement based on Public Law 99-272 and Public Law 101-506. Reviews conducted at the request of the third party payor do not generate records protected by 38 U.S.C. 5705 and these regulations since the reviews are not undertaken as part of the VA's quality assurance program. Compliance with applicable patient record confidentiality statutes is, of course, necessary.

The Secretary hereby certifies that this proposed regulatory amendment

will not, if promulgated, have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. §§ 601-612. The reasons for this certification are that the proposed regulatory amendment is for the express purpose of implementing 38 U.S.C. 5705 which protects particular records generated by the VA medical quality assurance program; affects only confidential VA records; and imposes no regulatory burdens on small entities. Pursuant to 5 U.S.C. § 605(b), this proposed regulatory amendment is therefore exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

There is no Catalog of Federal Domestic Assistant Number.

List of Subjects in 38 CFR Part 17

Alcoholism, Claims, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs, Health, Health care, Health facilities, Health professions, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Veterans.

Approved: October 4, 1994.

James Brown,
Secretary of Veterans Affairs.

For the reasons set forth in the preamble, VA amends 38 CFR Part 17 as follows:

PART 17—MEDICAL

1. The authority citation for Part 17 is revised to read as follows:

Authority: 38 U.S.C. 501, 5705.

2. Sections 17.500 and 17.501 and the undesignated center heading preceding § 17.500 are revised; § 17.502 is added; §§ 17.503 through 17.510 are revised; § 17.511 is added; and §§ 17.512 through 17.541 are removed as follows:

Confidentiality of Healthcare Quality Assurance Review Records

§ 17.500 General.

(a) Section 5705, title 38, United States Code was enacted to protect the integrity of the VA's medical quality assurance program by making confidential and privileged certain records and documents generated by this program and information contained therein. Disclosure of quality assurance records and documents made confidential and privileged by 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511 may only be made in accordance with the provisions of 38 U.S.C. 5705 and those regulations.

(b) The purpose of the regulations in §§ 17.500 through 17.511 is to specify

and provide for the limited disclosure of those quality assurance documents which are confidential under the provisions of 38 U.S.C. 5705.

(c) For purposes of the regulations in §§ 17.500 through 17.511, the VA's medical quality assurance program consists of systematic healthcare reviews carried out by or for VA for the purpose of improving the quality of medical care or improving the utilization of healthcare resources in VA medical facilities. These review activities may involve continuous or periodic data collection and may relate to either the structure, process, or outcome of health care provided in the VA.

(d) Nothing in the regulations in §§ 17.500 through 17.511 shall be construed as authority to withhold any record or document from a committee or subcommittee of either House of Congress or any joint committee or subcommittee of Congress, if such record or document pertains to any matter within the jurisdiction of such committee or joint committee.

(e) The regulations in §§ 17.500 through 17.511 do not waive the sovereign immunity of the United States, and do not waive the confidentiality provisions and disclosure restrictions of 38 U.S.C. 5705. (Authority: 38 U.S.C. 5705)

§ 17.501 Confidential and privileged documents.

(a) Documents and parts of documents are considered confidential and privileged if they were produced by or for the VA in the process of conducting systematic healthcare reviews for the purpose of improving the quality of health care or improving the utilization of healthcare resources in VA healthcare facilities and meet the criteria in paragraphs (b) and (c) of this section. The four classes of healthcare quality assurance reviews with examples are:

- (1) Monitoring and evaluation reviews conducted by a facility:
- (i) Medical records reviews,
- (ii) Drug usage evaluations,
- (iii) Blood usage reviews,
- (iv) Surgical case/invasive procedure reviews,
- (v) Service and program monitoring including monitoring performed by individual services or programs, several services or programs working together, or individuals from several services or programs working together as a team,
- (vi) Mortality and morbidity reviews,
- (vii) Infection control review and surveillance,
- (viii) Occurrence screening,
- (ix) Tort claims peer reviews (except reviews performed to satisfy the

requirements of a governmental body or a professional health care organization which is licensing practitioners or monitoring their professional performance).

(c) Admission and continued stay reviews.

(d) Diagnostic studies utilization reviews.

(e) Reports of special incidents (VA Form 10-2633 or similar forms) and follow-up documents unless developed during or as a result of a Board of Investigation.

(2) Focused reviews which address specific issues or incidents and which are designated by the reviewing office at the outset of the review as protected by 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511: Focused reviews may be either:

(i) Facility focused reviews;

(ii) VA Central Office or Regional focused reviews;

(3) VA Central Office or Regional general oversight reviews to assess facility compliance with VA program requirements if the reviews are designated by the reviewing office at the outset of the review as protected by 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511; and

(4) Contracted external reviews of care, specifically designated in the contract or agreement as reviews protected by 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511.

(b) The Under Secretary for Health, Regional Director or Facility Director will describe in advance in writing those quality assurance activities included under the classes of healthcare quality assurance reviews listed in paragraph (a) of this section. Only documents and parts of documents resulting from those activities which have been so described are protected by 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511. If an activity is not described in a VA Central Office or Regional policy document, this requirement may be satisfied at the facility level by description in advance of the activity and its designation as protected in the facility quality assurance plan or other policy document.

(c) Documents and parts of documents generated by activities which meet the criteria in paragraphs (a) and (b) of this section shall be confidential and privileged only if they:

(1) Identify, either implicitly or explicitly, individual practitioners, patients, or reviewers except as provided in paragraph (g)(6) of this section; or

(2) Contain discussions relating to the quality of VA medical care or utilization

of VA medical resources by healthcare evaluators during the course of a review of quality assurance information or data, even if they do not identify practitioners, patients, or reviewers; or

(3) Are individual committee, service, or study team minutes, notes, reports, memoranda, or other documents either produced by healthcare evaluators in deliberating on the findings of healthcare reviews, or prepared for purposes of discussion or consideration by healthcare evaluators during a quality assurance review; or

(4) Are memoranda, letters, or other documents from the medical facility to the Regional Director or VA Central Office which contain information generated by a quality assurance activity meeting the criteria in § 17.501 (a) and (b); or

(5) Are memoranda, letters, or other documents produced by the Regional Director or VA Central Office which either respond to or contain information generated by a quality assurance activity meeting the criteria in § 17.501 (a) and (b).

(d) Documents which meet the criteria in this section are confidential and privileged whether they are produced at the medical facility, Regional or VA Central Office levels, or by external contractors performing healthcare quality assurance reviews.

(e) Documents which are confidential and privileged may be in written, computer, electronic, photographic or any other form.

(f) Documents which contain confidential and privileged material in one part, but not in others, such as Clinical Executive Board minutes, should be filed and maintained as if the entire document was protected by 38 U.S.C. 5705. This is not required if the confidential and privileged material is deleted.

(g) The following records and documents and parts of records and documents are not confidential even if they meet the criteria in paragraphs (a) through (c) of this section:

(1) Statistical information regarding VA healthcare programs or activities that does not implicitly or explicitly identify individual VA patients or VA employees or individuals involved in the quality assurance process;

(2) Summary documents or records which only identify study topics, the period of time covered by the study, criteria, norms, and/or major overall findings, but which do not identify individual healthcare practitioners, even by implication;

(3) The contents of Credentialing and Privileging folders as described in VACO policy documents (38 U.S.C.

5705-protected records shall not be filed in Credentialing and Privileging folders);

(4) Records and documents developed during or as a result of Boards of Investigations;

(5) Completed patient satisfaction survey questionnaires and findings from patient satisfaction surveys;

(6) Records and documents which only indicate the number of patients treated by a practitioner, either by diagnosis or in aggregate, or number of procedures performed by a practitioner, either by procedure or in aggregate;

(7) Records and documents developed during or as a result of reviews performed to satisfy the requirements of a governmental body or a professional healthcare organization which is licensing practitioners or monitoring their professional performance, e.g., National Practitioner Data Bank, Federation of State Medical Boards, and National Council of State Boards of Nursing;

(8) Documents and reports developed during or as a result of site visits by the Office of the Medical Inspector except to the extent that the documents and reports contain information that meets the criteria described in this section and are produced by or for VA by other than the Office of Medical Inspector;

(9) External reviews conducted by VA Central Office or a Region other than those designated by the reviewing office under paragraph (a)(2) or (a)(3) of this section as protected by 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511;

(10) Documents and reports of Professional Standards Boards, Credentialing Committees, Executive Committees of Medical Staff, and similar bodies, insofar as the documents relate to the credentialing and privileging of practitioners;

(11) Documents and reports developed during or as a result of data validation activities;

(12) Documents and reports developed during or as a result of occupational health monitoring;

(13) Documents and reports developed during or as a result of safety monitoring not directly related to the care of specified individual patients;

(14) Documents and reports developed during or as a result of resource management activities not directly related to the care of specified individual patients; and

(15) Information and records derived from patient medical records or facility administrative records, which are not protected by 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511, may be sent or communicated to a third

party payor who has asked for this information in response to a VA request for reimbursement based on Public Law 99-272 and Public Law 101-508. Reviews conducted at the request of the third party payor do not generate records protected by 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511 since the reviews are not undertaken as part of the VA's quality assurance program.

(Authority: 38 U.S.C. 5705)

§ 17.502 Applicability of other statutes.

(a) Disclosure of quality assurance records and documents which are not confidential and privileged under 38 U.S.C. 5705 and the confidentiality regulations in §§ 17.500 through 17.511 will be governed by the provisions of the Freedom of Information Act, and, if applicable, the Privacy Act and any other VA or federal confidentiality statutes.

(b) When included in a quality assurance review, confidential records protected by other confidentiality statutes such as 5 U.S.C. 552a (the Privacy Act), 38 U.S.C. 7332 (drug and alcohol abuse, sickle cell anemia, HIV infection), and 38 U.S.C. 5701 (veterans names and addresses) retain whatever confidentiality protection they have under these laws and applicable regulations and will be handled accordingly. To the extent that information protected by 38 U.S.C. 5701 or 7332 or the Privacy Act is incorporated into quality assurance records, the information in the quality assurance records is still protected by these statutes.

(Authority: 38 U.S.C. 5705)

§ 17.503 Improper disclosure.

(a) Improper disclosure is the disclosure of confidential and privileged healthcare quality assurance review records or documents (or information contained therein), as defined in § 17.501, to any person who is not authorized access to the records or documents under the statute and the regulations in §§ 17.500 through 17.511.

(b) "Disclosure" means the communication, transmission, or conveyance in any way of any confidential and privileged quality assurance records or documents or information contained in them to any individual or organization in any form by any means.

(Authority: 38 U.S.C. 5705)

§ 17.504 Disclosure methods.

(a) Disclosure of confidential and privileged quality assurance records and documents or the information contained

therein outside VA, where permitted by the statute and the regulations in §§ 17.500 through 17.511, will always be by copies, abstracts, summaries, or similar records or documents prepared by the Department of Veterans Affairs and released to the requester. The original confidential and privileged quality assurance records and documents will not be removed from the VA facility by any person, VA employee or otherwise, except in accordance with § 17.508(c) or where otherwise legally required.

(b) Disclosure of confidential and privileged quality assurance records and documents to authorized individuals under either § 17.508 or § 17.509 shall bear the following statement: "These documents or records (or information contained herein) are confidential and privileged under the provisions of 38 U.S.C. 5705, which provide for fines up to \$20,000 for unauthorized disclosures thereof, and the implementing regulations. This material shall not be disclosed to anyone without authorization as provided for by that law or the regulations in §§ 17.500 through 17.511."

(Authority: 38 U.S.C. 5705)

§ 17.505 Disclosure authorities.

The VA medical facility Director, Regional Director, Under Secretary for Health, or their designees are authorized to disclose any confidential and privileged quality assurance records or documents under their control to other agencies, organizations, or individuals where 38 U.S.C. 5705 or the regulations in §§ 17.500 through 17.511 expressly provide for disclosure.

(Authority: 38 U.S.C. 5705)

§ 17.506 Appeal of decision by Veterans Health Administration to deny disclosure.

When a request for records or documents subject to the regulations in §§ 17.500 through 17.511 is denied in whole or in part by the VA medical facility Director, Regional Director or Under Secretary for Health, the VA official denying the request in whole or in part will notify the requester in writing of the right to appeal this decision to the General Counsel of the Department of Veterans Affairs within 60 days of the date of the denial letter. The final Department decision will be made by the General Counsel or the Deputy General Counsel.

(Authority: 38 U.S.C. 5705)

§ 17.507 Employee responsibilities.

(a) All VA employees and other individuals who have access to records designated as confidential and

privileged under 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511 will treat the findings, views, and actions relating to quality assurance in a confidential manner.

(b) All individuals who have had access to records designated as confidential and privileged under 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511 will not disclose such records or information therein to any person or organization after voluntary or involuntary termination of their relationship to the VA.

(Authority: 38 U.S.C. 5705)

§ 17.508 Access to quality assurance records and documents within the agency.

(a) Access to confidential and privileged quality assurance records and documents within the Department pursuant to this section is restricted to VA employees (including consultants and contractors of VA) who have a need for such information to perform their government duties or contractual responsibilities and who are authorized access by the VA medical facility Director, Regional Director, the Under Secretary for Health, or their designees or by the regulations in §§ 17.500 through 17.511.

(b) To foster continuous quality improvement, practitioners on VA rolls, whether paid or not, will have access to confidential and privileged quality assurance records and documents relating to evaluation of the care they provided.

(c) Any quality assurance record or document, whether confidential and privileged or not, may be provided to the General Counsel or any attorney within the Office of General Counsel, whenever located. These documents may also be provided to a Department of Justice (DOJ) attorney who is investigating a claim or potential claim against the VA or who is preparing for litigation involving the VA. If necessary, such a record or document may be removed from the VA medical facility to the site where the General Counsel or any attorney within the Office of General Counsel or the DOJ attorney is conducting an investigation or preparing for litigation.

(d) Any quality assurance record or document or the information contained therein, whether confidential and privileged or not, will be provided to the Department of Veterans Affairs Office of Inspector General upon request. A written request is not required.

(e) To the extent practicable, documents accessed under paragraph (b) of this section will not include the

identity of peer reviewers. Reasonable efforts will be made to edit documents so as to protect the identities of reviewers, but the inability to completely do so will not bar access under paragraph (b).

(f) No individual shall be permitted access to confidential and privileged quality assurance records and documents identified in § 17.501 unless such individual has been informed of the penalties for unauthorized disclosure. Any misuse of confidential and privileged quality assurance records or documents shall be reported to the appropriate VHA official, e.g., Service Chief, Medical Center Director.

(g) In general, confidential and privileged quality assurance records and documents will be maintained for a minimum of 3 years and may be held longer if needed for research studies or quality assurance or legal purposes. (Authority: 38 U.S.C. § 708)

§ 17.502 Authorized disclosure: Non-Department of Veterans Affairs requests.

(a) Requests for confidential and privileged quality assurance records and documents from organizations or individuals outside VA must be made to the Department and must specify the nature and content of the information requested, to whom the information should be transmitted or disclosed, and the purposes listed in paragraphs (b) through (j) of this section for which the information requested will be used. In addition, the requestor will specify to the extent possible the beginning and final dates of the period for which disclosure or access is requested. The request must be in writing and signed by the requestor. Except as specified in paragraphs (b) and (c) of this section, these requests should be forwarded to the Director of the facility in possession of the records or documents for response. The procedures outlined in 38 CFR 1.500 through 1.564 will be followed where applicable.

(b) Disclosure shall be made to Federal agencies upon their written request to permit VA's participation in healthcare programs including healthcare delivery, research, planning and related activities with the requesting agencies. Any Federal agency may apply to the Under Secretary for Health for approval. If the VA decides to participate in the healthcare program with the requestor, the requesting agency will enter into an agreement with VA to ensure that the agency and its staff will ensure the confidentiality of any quality assurance records or documents shared with the agency.

(c) Qualified persons or organizations, including academic institutions,

engaged in healthcare program activities shall, upon request to and approval by the Under Secretary for Health, Regional Director, medical facility Director, or their designees, have access to confidential and privileged medical quality assurance records and documents to permit VA participation in a healthcare activity with the requestor, provided that no records or documents are removed from the VA facility in possession of the records.

(d) When a request under paragraphs (b) or (c) of this section concerns access for research purposes, the request, together with the research plan or protocol, shall first be submitted to and approved by an appropriate VA medical facility Research and Development Committee and then approved by the Director of the VA medical facility. The VA medical facility staff together with the qualified person(s) conducting the research shall be responsible for the preservation of the anonymity of the patients, clients, and providers and shall not disseminate any records or documents which identify such individuals directly or indirectly without the individual's consent. This applies to the handling of data or information as well as reporting or publication of findings. These requirements are in addition to other applicable protections for the research.

(e) Individually identified patient medical record information which is protected by another statute is provided in § 17.502 may not be disclosed to a non-VA person or organization, including disclosure for research purposes under paragraph (d), except as provided in that statute.

(f) Under paragraph (b), the Under Secretary for Health or designee or, under paragraph (c), the Under Secretary for Health, Regional Director, medical facility Director, or their designees may approve a written request if it meets the following criteria:

- (1) Participation by VA will benefit VA patient care; or
 - (2) Participation by VA will enhance VA medical research; or
 - (3) Participation by VA will enhance VA health services research; or
 - (4) Participation by VA will enhance VA healthcare planning or program development activities; or
 - (5) Participation by VA will enhance related VA healthcare program activities; and
 - (6) Access to the record by the requestor is required for VA to participate in a healthcare program with the requestor.
- (g) Protected quality assurance records or documents, including records pertaining to a specific individual, will

for purposes authorized under law be disclosed to a civil or criminal law enforcement governmental agency or instrumentality charged under applicable law with the protection of public health or safety, including state licensing and disciplinary agencies, if a written request for such records or documents is received from an official of such an organization. The request must state the purposes authorized by law for which the records will be used. The Under Secretary for Health, Regional Director, medical facility Director, or their designees will determine the extent to which the information is disclosable.

(h) Federal agencies charged with protecting the public health and welfare, federal and private agencies which engage in various monitoring and quality control activities, agencies responsible for licensure of individual health care facilities or programs, and similar organizations will be provided confidential and privileged quality assurance records and documents if a written request for such records or documents is received from an official of such an organization. The request must state the purposes for which the records will be used. The Under Secretary for Health, Regional Director, medical facility Director, or their designees will determine the extent to which the information is disclosable.

(i) JCAHO (Joint Commission on Accreditation of Healthcare Organizations) survey teams and similar national accreditation agencies or boards and other organizations requested by VA to assess the effectiveness of quality assurance program activities or to consult regarding these programs are entitled to disclosure of confidential and privileged quality assurance documents with the following qualifications:

- (1) Accreditation agencies which are charged with assessing all aspects of medical facility patient care, e.g., JCAHO, may have access to all confidential and privileged quality assurance records and documents.
- (2) Accreditation agencies charged with more narrowly focused review (e.g., College of American Pathologists, American Association of Blood Banks, Nuclear Regulatory Commission, etc.) may have access only to such confidential and privileged records and documents as are relevant to their respective focus.
- (3) Confidential and privileged quality assurance records and documents shall be released to the General Accounting Office if such records or documents pertain to any matter within its jurisdiction.

(k) Confidential and privileged quality assurance records and documents shall be released to both VA and non-VA healthcare personnel upon request to the extent necessary to meet a medical emergency affecting the health or safety of any individual.

(l) For any disclosure made under paragraphs (a) through (i) of this section, the name of and other identifying information regarding any individual VA patient, employee, or other individual associated with VA shall be deleted from any confidential and privileged quality assurance record or document before any disclosure under these quality assurance regulations in §§ 17.500 through 17.511 is made. If disclosure of such name and identifying information would constitute a clearly unwarranted invasion of personal privacy.

(m) Disclosure of the confidential and privileged quality assurance records and documents identified in § 17.501 will not be made to any individual or agency until that individual or agency has been informed of the penalties for unauthorized disclosure or redisclosure. (Authority: 38 U.S.C. 5705)

§ 17.510 Redisclosure.

No person or entity to whom a quality assurance record or document has been disclosed under § 17.506 or § 17.509 shall make further disclosure of such record or document except as provided for in 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511.

(Authority: 38 U.S.C. 5705)

§ 17.511 Penalties for violations.

Any person who knows that a document or record is a confidential and privileged quality assurance document or record described in §§ 17.500 through 17.511 and willfully discloses such confidential and privileged quality assurance record or document or information contained therein, except as authorized by 38 U.S.C. 5705 or the regulations in §§ 17.500 through 17.511, shall be fined not more than \$5,000 in the case of a first offense and not more than \$20,000 in the case of each subsequent offense.

(Authority: 38 U.S.C. 5705)

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[40-FRL-5092-4]

National Emission Standards for Hazardous Air Pollutants for Source Categories: Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry and Other Processes Subject to the Negotiated Regulation for Equipment Leaks

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of partial stay and reconsideration.

SUMMARY: Today's action announces a partial 3-month stay of certain national emission standards for hazardous air pollutants for certain sources. The effectiveness of the "National Emission Standards for Hazardous Air Pollutants for Source Categories: Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry and Other Processes Subject to the Negotiated Regulation for Equipment Leaks" (April 22, 1994) and (June 6, 1994)

(collectively known as the "hazardous organics NESHAP" or the "HON"), including the applicable compliance dates, is stayed for 3 months pending reconsideration. The EPA is issuing this stay pursuant to Clean Air Act section 307(d)(7)(B), 42 U.S.C. 7607(d)(7)(B), which provides the Administrator authority to stay the effectiveness of a rule during reconsideration.

Elsewhere in the Proposed Rules Section of today's Federal Register EPA proposes to date compliance with the HON for sources meeting certain criteria, and to extend the compliance date for sources affected by today's stay, for as long as is necessary to complete the rulemaking granting this deferral.

This stay affects only those sources for which the owner or operator makes a representation in writing to the Administrator that the resolution of the area source definition issues could have an effect on the compliance status of the source with respect to subparts F, G, H, and I of part 63.

EFFECTIVE DATE: October 24, 1994.

FOR FURTHER INFORMATION CONTACT: Mr. Tim Smith at (919) 541-4718, Emission Standards Division (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

SUPPLEMENTARY INFORMATION:

I. Background

On April 22, 1994 (59 FR 19402), and June 6, 1994 (59 FR 29196), the Environmental Protection Agency promulgated in the Federal Register a NESHAP for the synthetic organic chemical manufacturing industry, and for several other processes subject to the equipment leaks portion of the rule. These regulations were promulgated as subparts F, G, H, and I in 40 CFR part 63, and are commonly referred to as the hazardous organics NESHAP, or the HON. Section 63.100 of the rule provides that the rule is applicable to chemical manufacturing process units that, among other requirements, "are located at a plant site that is a major source as defined in section 112(a) of the Act."

Section 112(a) of the Act defines a "major source" as "any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants." Any stationary source that does not emit, or have the potential to emit, these quantities, is defined by the Act as an "area source." On March 16, 1994, EPA promulgated, in subpart A to 40 CFR part 63, a definition of "potential to emit." A key aspect of the potential to emit definition is that restrictions must be federally enforceable.

The EPA is in the process of clarifying the administrative procedures that can be used by source owners and operators to create federally enforceable restrictions on potential to emit. However, in the interim there may be sources that would qualify as area sources exempt from the HON which do not have the ability to demonstrate to EPA that their potential to emit is below major source levels. A petition for reconsideration has been submitted to EPA requesting that the HON be revised such that sources that may be area are not required to comply with the HON due to their inability to prove that they are area sources. For this reason EPA is staying the HON for 3 months in order to respond to the petition for reconsideration and revise the rule as necessary to resolve this issue.

The EPA believes that the majority of HON-affected sources emit well above major source levels. Accordingly, today's stay does not affect all sources.

Dr. GARTHWAITE. We'll try to fight through the legal issues here. But it is our intention clearly to give every patient their complete medical record if they request it, and to provide a complete medical record to any other practitioners they wish to have treat them.

And that has always been the case. The problem we get into is that other people occasionally request the records or it's sort of by word of mouth, and then we inadvertently release it to someone they don't want them going to, and it causes all sorts of havoc.

So our biggest problem is training all our staff not to let them go without a signed consent. Because I don't want my medical records, and I'm sure you don't want your medical records, being given to just anyone. And so it's a fine line between protecting the confidentiality of the patient, which is a critical and important part of trust, and allowing the records to get to where they need to go.

We apologize for it, if, in any way, we've gotten in the way of a patient getting the record to where they want it to go.

Mrs. CHENOWETH. Thank you, Doctor.

And I just have—I notice the yellow light, and I just have one more very quick question. We have had a multitude of complaints come into my office about not being able to get medical records. But I just want to ask you would you judge, from your professional work, that a sudden, severe onset of abdominal pain; sudden, unanticipated, uncontrollable bowel evacuation; sudden, severe headache; and a loss of consciousness that was sudden but prolonged; and then followed by eruption over the next few weeks of subcutaneous but benign lesions, multiple, in the forehead—

I bring this up because the patient I'm talking about here was asked to go to a mental health hospital to have this kind of physical ailment taken care of. Doctor, my concern is that—I wonder if there isn't some sort of threshold that we might be able to meet soon that if a patient exhibits even one of these symptoms that could be related to Gulf War Syndrome, that immediately they're put in a classification of Gulf War Syndrome victims and treated with immediate attention.

I think that's what our veterans need, what would help satisfy me anyway on this committee; and I'd like to work with you on that and the Chairman. Of course, this is at his pleasure. But this threshold is something that I think is really needed, because there's so much frustration now mounting out there in the field where the rubber meets the road.

Dr. GARTHWAITE. Sure. It's a great concern to us if any veteran goes to a VA medical center and has less than an ideal experience. Individual cases we're more than happy to review, and we can do that at the local level; and we can get involved in Washington, if that's important.

But we're very interested in that. As we enhance our computer capabilities, I think the ability to have a veteran walk into any VA medical center and to have us know basically what's wrong with them and take that into account as we treat them, is becoming increasingly possible.

And we're excited about some of the developments we're making in those areas. So I think that if you go to the same place presumably and the medical record is immediately available, then it

should be possible to understand the background that goes with the patient.

And we'll continue to work through those issues. And if you have specific ones, please let us know.

Mrs. CHENOWETH. Thank you, Doctor.

Thank you, Mr. Chairman.

The CHAIRMAN. The gentleman from Texas, Mr. Reyes.

Mr. REYES. Thank you, Mr. Chairman.

I have a few questions. One of my first questions concerns the region of the world where this all occurred. And since there has been—or there have been incidents in the past—for instance, the Iran/Iraqi war where they used extensively both biological and chemical weapons and are well documented—is there not, in the Department of Defense, a division or a department or a section that—whose responsibility it is to research and anticipate some of these types of chemicals and weapons that might be used against our troops before we deploy?

Dr. JOSEPH. Yes, there is. I'm not aware that there's a known use of biological agents in the Iran/Iraq war. Chemicals agents, yes; but that's not really your question. The Department has, on the medical side of intelligence, a quite sophisticated capability to know what is where and what threats might be expected.

Mr. REYES. In this particular case, before we deployed to the Gulf War, what—was this system in place and activated; and in fact, is there a record somewhere of what was anticipated that we would run up against?

Dr. JOSEPH. Yes, yes, yes, and yes. There was great anxiety and concern at the deployment about the risk that the troops were facing from chemical weapons. In fact, that's probably a major issue in many of the symptoms of people sitting under that risk for 6 months.

Dr. ROSTKER. Our troops were extremely well prepared. For example, in the 24th Infantry Division, they didn't wear regular utilities. Their standard issue was gear that had carbon inside of it, the standard chemical gear. And that's the way they went into battle.

Same way with the Marines. In fact, we were probably so primed that we were seeing chemical agents in every cloud in every dust storm. And that's part of the difficulty in sorting all of this out.

Mr. REYES. Well, and that leads me to my next question, which is the—I think the break down in trust given what has occurred post-Gulf War—

Dr. ROSTKER. Part of the break down—for example, we had a chemical alarm that was very sensitive. It was called an M-8 alarm. We've demonstrated the alarm for our veterans' service organizations. Except every time you change the battery, you had to test the alarm.

Several times a day, you had to take the little filter out of a compartment and clean the filter. And every time you put the filter back, you tested the alarm. It was like a fire alarm in our house that we had to tend to two or three times a day.

You get to the point where you're not sure what to do with the alarm. We now are moving towards alarms that do not require us to sound the siren to change a battery, to change a filter. So there's

a whole range of things that did not work as well as we had hoped they would have worked.

Mr. REYES. As a result of whatever this mixture or combination of things that didn't work exactly as we had planned or anticipated, the bottom line to a degree is that we do have a mixture of conditions or of symptoms that as a result of whatever occurred, maybe the battery was being changed or maybe the troops or whoever was in charge became so conditioned to the fact that this mechanical device was not working properly, that in that context, our troops did suffer exposure.

Part of what, and I'll just be perfectly frank with you. Part of the frustration that we hear from Gulf War veterans is the fact that they feel more than a little insulted at the fact that a lot of this is being blamed on stress. Commander Nier earlier mentioned that specifically.

Then secondly, are we not at a point where you could support the affirmation that in fact a Gulf War syndrome does exist or that we ought to at least entertain instead of just blatantly saying, which is what I'm hearing and correct me if I'm wrong, that there does not exist nor do we anticipate in the near future having the ability to definitively say yes, Gulf War syndrome is in fact—

Dr. ROSTKER. Let me answer the exposure question. I think Dr. Joseph can answer the syndrome question.

We would have to say today that we're just not sure that we know that our troops may have been exposed to chemical agents at Khamisiyah. We are investigating all of the other cases through the veterans hotlines and others that have been reported, to try to understand the situation around the operation so that we're not relying on a single report. We're trying to put it into context. It's those reports that we'll be making available to you.

So we are trying to weave this tapestry to get the best assessment of where and how our troops may have been exposed.

To the issue of syndrome.

Dr. JOSEPH. Let me say first that there hasn't been, from either agency, a blatant or "off the cuff" no it's not. The conclusion about a syndrome or the absence of a syndrome—which is much more widespread than just the two agencies sitting here—comes after a lot of hard careful work and extensive analysis. Whether it's right or wrong, it's not blatant or "tossed off."

Second, while I believe that no one in this room has experienced one, a chemical attack or an exposure to chemical weapons in any significant quantity is a rather dramatic event. It would not be logical to expect that had troops been exposed to a weaponized attack that it would have gone unnoticed. What we do know, from not only what people have written about but also from the First World War, and from what we know occurred in Iran, Iraq, and what we know from experimental work with primates at Cipra, we would expect to have a lot of very visible casualties.

So what the issue comes down to, then, is whether there might have been sub-clinical exposures to minute amounts of agent that did not give rise to any observable symptoms at the time, but might be responsible for illness some months or years later.

As I think we said earlier, the existing research base says that that does not happen; but the research base is inadequate. That's

why we need to continue to do more research on that particular question, to see if it might be so. I think it would be very unlikely that we would have missed, or that people who were there at the time would have missed, an exposure of the type you have described. There would have been many, and many severe, casualties.

Mr. REYES. But you do agree that the possibility exists in the context of you know, what has been described as mechanical failures and things along those lines. I mean I am asking could it be possible that we could have missed it?

Dr. ROSTKER. Let's take the alarms, for example. We would have expected that the alarm might have gone off and there would be other factors we could have looked at, physical factors in terms of sick people.

If your folks' smoke alarm goes off in your house, you don't immediately run and file a claim with the insurance company because your house burnt down. You look to see where the alarm might have been, what might have caused the alarm. It sets you off. It's exactly that. It's an alarm. It makes you look, stop, look and listen. It makes you check. That's what the alarms did in the Gulf. It made people check, but there was no corroboration. That's what we're trying to put together to either demonstrate that there was corroboration or demonstrate there wasn't corroboration.

We take the alarms, particularly the most sensitive alarms, very seriously. We're trying to document what can be learned about the operations that these alarms were part of.

Mr. REYES. Thank you, Mr. Chairman.

The CHAIRMAN. The gentleman's time has expired. Now to the gentleman that's waited so patiently, from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman. In the interest of time, hopefully I won't have to take anywhere near the 5 minutes, mainly because Mr. Reyes almost like he was reading my mind, asked many of the questions, at least the initial portion of many of the questions that I would ask.

Many of us, the chairman and I and others, tussled with the Agent Orange problem, still with us actually for years. I am not sure what we learned from that. Now we have this particular problem. I don't know why I have the feeling quite frankly, maybe it goes to lack of credibility, lack of confidence, faith, et cetera, but I have the feeling in the next war that our boys and girls might be in, we're going to have the same sort of problems. It will be a new syndrome coming out of the woodwork.

I just wonder are we prepared? Dr. Jackson, you were not in your current position back during the Gulf War. Were you?

Dr. JACKSON. That's correct.

Mr. BILIRAKIS. That's correct. Dr. Rostker or Dr. Joseph have already said they weren't. In your opinion, did we do things right? Now maybe we didn't have adequate research. Dr. Joseph talked about plowing ground and that sort of thing. But if the ground had been plowed prior to that point in time, was everything in place to do things right? Were the environmental people adequately coordinated with? Was your office, your predecessors adequately coordinated with and what not?

I mean the Gulf War did not take place just like that. There was an awful lot of planning, at least from a military standpoint at

least, that went into it. I mean it was something that we could have adequately planned for. Maybe we did, I don't know.

But you know, this committee is focusing on, and thanks to the chairman, on reviewing the health consequences of service during the Persian Gulf War. That is of course the function.

But wouldn't it be nice if we didn't have that problem to deal with?

Dr. ROSTKER. Sir, I would say we were very well prepared for the chemical and to a lesser extent, the biological threat, but particularly to the chemical threat.

What we were not well prepared for is to fight the post-war battle over Gulf War illnesses.

Mr. BILIRAKIS. What do you mean by that?

Dr. ROSTKER. I mean we did not have an adequate means of capturing where our people were, even at the unit level. So to this day, we are not adequate in telling you where a given unit was on a given day or where individuals were on a day, which is really very necessary to do the kind of epidemiological work.

Mr. BILIRAKIS. In other words, we could not have forecast where particular—

Dr. ROSTKER. We should have been able to.

Mr. BILIRAKIS. We should have been able to.

Dr. ROSTKER. But in fact, the people who put the database together have told us that they had a better ability to do that during Vietnam and World War II and Korea than they had in the Gulf because they had made some changes that actually hurt our ability to put that kind of information together.

So one of the charges that we have for the future is to identify those cases and areas where changes need to be made, and make sure we put into place those changes. But there are other examples in environmental monitoring, which is better today. We collect and maintain serum samples which we didn't do.

I think Dr. Joseph can give you a number of things we do today that we didn't do during the Gulf.

Dr. JOSEPH. I think, Mr. Bilirakis, that many of the improvements we have made in force protection, medical force protection, are with the wisdom of hindsight. But one thing that I think we ought to have known to be prepared about at the time. That one thing has to do with a smoother and more intensive connection between operational intelligence and medical.

As I look back now in hindsight, I can see some things we need to do and things we have done in the process.

Mr. BILIRAKIS. That's really what I am getting at.

Dr. JOSEPH. As I look back in hindsight and learn about how the links were made, or were not made, between the operational intelligence that was coming in and the medical coverage, care, and response, that we could have known better then that we should have done the linking better. Most of the rest is hindsight.

Mr. BILIRAKIS. Well my time is just about up and this panel has taken a lot of time. It's our fault, not yours. I appreciate your testimony. It's been very good.

But I guess, you know, I am looking forward to the day when we can have one of these, where is the next war going to be that we don't know, hopefully never, but obviously these things take place.

It might be in the jungles of South America or something of that nature. We should have adequate intelligence and adequate communication and coordination of knowledge with the environmental people, with the health people and what not in order to be better prepared. Apparently we weren't, in spite of the fact that this war was sort of a planned thing, that we should have been able to do.

I am not trying to belittle it because I know it's a heck of a lot more complex than my knowledge would impart.

Well, thanks, Mr. Chairman.

The CHAIRMAN. Thank you, Mike.

I believe the gentlelady from Idaho has one brief follow-up question.

Mrs. CHENOWETH. Thank you for your indulgence, Mr. Chairman. I want to ask Dr. Jackson one quick question. I assume that the inoculations for anthrax and botulism were okayed by the FDA. I mean that's an assumption we can feel pretty safe with.

The second part of my question is, is there any ongoing studies with regards to the cumulative effects of the inoculations plus the application of whatever it was that they put on their skin when they were over there to make sure that nerve gas didn't affect them as quickly otherwise.

So I assume that the cumulative effect studies are going on and if they are, I would be very interested in taking a look at them too.

Dr. JACKSON. Multiple different questions there. Quickly, I would like to quickly put in the next time we deal with this it's very important to have the blood specimens before, during, and after people go.

When I was a young epidemiologist and they were going to send me off to deal with this or that, they took a whole liter of blood to make sure that when we caught something out there that they know what was going on with us. I think that's very important. In the rush, the next time we prepare for war, people will begin to think it's not so important this time around.

The second question about vaccines, I know that the advisory panel to the armed forces has been dealing with how many are really needed, and what's going on with these mixtures. It's a difficult issue because we certainly don't want to put someone in harm's way and then find out oh, we really should have immunized them against this or that.

On the question of research, it is very important to look at these cumulative issues. It's not easy research because of just the nature of when you start adding things up, it becomes very expensive and very complicated very quickly. There is some of that underway.

On the issue of drugs and approval, I'm going to turn to my FDA colleague, Dr. Nightengale.

Dr. NIGHTENGAL. Thank you. I guess what I can say is what we had done to help prepare DOD in this. We certainly had approved a botulinum toxoid for use through a special investigational protocol with information to be given to the troops. I understand that that was used.

As far as the anthrax vaccine is concerned, my understanding is that they did use an approved vaccine on the troop, a licensed vaccine.

Dr. JOSEPH. The other agent, of course, was pyridostigmine bromide, which is an FDA-approved drug; but not approved for the specific purpose of nerve gas preventive treatment, because there is no research on that. We sought and obtained FDA approval to use that drug. That was challenged in court. We won in court.

I would like to, if I may, take 30 seconds more?

The CHAIRMAN. Very briefly, sir. Please.

Dr. JOSEPH. When we get to this part of the discussion about the immunizations and the nerve gas prevention treatment, it's important to say—in fairness to the people who were here then and made those decisions, and I believe they made the right decisions—we knew he (Saddam Hussein) had those agents. He knew we knew he had those agents. There was significant and well-based concern that he might employ them. The people who made those decisions then, medically and the line commanders, made those decisions to try to protect the lives of our troops.

I don't think any of us would want to be in this hearing today knowing what we knew then, if we did not protect our troops as best we could with what we had and he had used those nerve agents.

That is the balance that often gets forgotten in this discussion.

The CHAIRMAN. Dr. Nightengale.

Dr. NIGHTENGAL. Yes. Just to shed some light on actually the last statement. There is in the letter from Dr. Mendez, who preceded Dr. Joseph in that position, there's a letter that we published as part of our Federal Register notice when we put the interim rule in place that actually talks about the concern about the use of the chemical and biological warfare. I can give you that for the record. It's in the public domain.

Dr. Joseph mentioned briefly the pyridostigmine bromide. While it is an approved drug for other uses, this was handled exactly the same way the botulinum toxoid was, in that it was handled through an IND, an investigational new drug procedure. There was a specific protocol approved for the use in the Persian Gulf, which is under the framework interim rule.

The CHAIRMAN. Thank you.

Mrs. CHENOWETH. Doctors, I just want to say that my main concern is, although each one of these individually were approved, the cumulative effects studies I think should be vigorous and enthusiastic. I hope you can share the information with the committee as soon as possible. Thank you.

The CHAIRMAN. Gentlemen and ladies, thank you very much. I am sure you can anticipate some questions in writing, if you would respond as expeditiously as possible, it would be greatly appreciated. Thank you very much for giving us your time.

If the next panel, number four, would come up. We have two panels and six witnesses to go. I would admonish the members to try to hold their questions as briefly as possible, please.

We have Mr. Puglisi, the Assistant Director of the National Veterans Affairs and Rehabilitation of the American Legion, Joseph Violante, the Deputy Legislative Director for the DAV, and Jeffrey Ford, the Executive Director for the National Gulf War Resource Center. If you would come to the table, please.

Let me remind you that your statements will be included in their entirety in the record. If you can summarize, it would be greatly appreciated. We have another panel to go.

The CHAIRMAN. Mr. Puglisi, would you like to start off?

STATEMENTS OF MATTHEW L. PUGLISI, ASSISTANT DIRECTOR, NATIONAL VETERANS AFFAIRS AND REHABILITATION, THE AMERICAN LEGION; JOSEPH A. VIOLANTE, DEPUTY LEGISLATIVE DIRECTOR, DISABLED AMERICAN VETERANS; AND JEFFREY S. FORD, EXECUTIVE DIRECTOR, NATIONAL GULF WAR RESOURCE CENTER

STATEMENT OF MATTHEW L. PUGLISI

Mr. PUGLISI. Yes, sir. Mr. Chairman, distinguished Members of the Committee, the American Legion appreciates the opportunity—

The CHAIRMAN. Pardon me just a minute. If those people that are finished would clear the room, please, so we can move on here very rapidly. We're running way behind time. Thank you very much.

Mr. PUGLISI. Again, thank you very much, Mr. Chairman and Members of the Committee for staying so late today. I know you have had a long day with the hearing this morning as well. The American Legion appreciates the opportunity to offer testimony concerning the final report of the Presidential Advisory Committee on Gulf War Veterans Illnesses or the PAC, as I'll refer to it throughout my testimony.

The Legion commends you, Mr. Chairman, for convening this hearing on a document that has and will continue to have a significant impact on how the Federal Government responds to Gulf War illnesses.

The PAC's final report is a thoughtful analysis of the Federal Government's response to and the nature of Gulf War illnesses. The compilation of clinical and epidemiological data is the most complete and well organized on this topic to date.

The PAC in its report has had a significant positive impact on some areas of the Federal Government's response to Gulf War illnesses, notably the Department of Defense's investigation into chemical and biological weapons exposures.

The final report has a number of limitations or weaknesses, however. Most notably, its inability to adequately evaluate the medical treatment provided to Gulf War veterans from DOD or to the Department of Veterans Affairs.

I would like to talk about the greatest strength of the report. The PAC will long be remembered for the impact it had on DOD's investigation of possible chemical and biological weapons exposures of US troops in the Persian Gulf. This impact can not be overstated. DOD maintained for over 5 years after the Gulf War, that there was no presence, no use, and no exposure of US troops to CBW agents in the Kuwaiti theater of operations. The three no's, as now famously described by the PAC.

DOD no longer maintains that position. It now has over 10 times the manpower devoted to this investigation, as Dr. Rostker talked about in the previous panel. The PAC's aggressive and thorough investigation and the articulate and damning staff reports sparked

the Pentagon to revamp its entire approach to Gulf War illnesses months before the final report was submitted to the President.

I would now like to address two limitations or weaknesses of the report. The PAC did not find a causal link between many of the well known risk factors associated with Gulf War illnesses except stress. The final report describes in detail the well-defined and well known psychological consequences of exposure to traumatic stress, post-traumatic stress disorder or PTSD, and the subsequent poor physical or physiological health found in PTSD patients.

However, except for two studies, PTSD does not appear as a major contributor to symptoms associated with Gulf War illnesses. This has been found by a number of epidemiological studies underway and completed conducted by the Centers for Disease Control, the Boston VA Environmental Hazard Center, the Iowa Persian Gulf Study Group, and the University of Texas.

All of these studies, except the Texas study, carefully screened veterans for PTSD. They did find PTSD in some veterans. However, all found veterans suffering from symptoms of fatigue, joint and muscle pain, headaches, et cetera, but these very veterans did not meet the criteria for PTSD.

PTSD does not explain Gulf War illnesses because those whose symptoms fall into Gulf War illness's very broad category do not suffer from PTSD according to most of the peer reviewed research reported to date.

The final report alludes to ongoing research that is investigating the link between non-traumatic stress and adverse physiological or physical health outcomes. This research is fascinating, and in its early stages. The final report recognizes this fact by carefully explaining that "scientists are beginning to unravel the physiological connection between the brain and various parts of the human body." Furthermore, that "some researchers suspect that the inadequate production of stress hormones and stress response occurs in some, not all humans with chronic fatigue syndrome and PTSD."

Suspensions are not data or scientific findings. The PAC's finding that stress is a likely cause of Gulf War illnesses is premature at best. One of the Nation's leading PTSD experts recently commented that "likely should not be used by the PAC to describe stress, not yet."

Overall, the PAC's final report accomplished the mission given to the PAC in its charter. Evaluate the Federal Government's response to Gulf War veterans illnesses. In some areas, the PAC had a significant positive impact on the Government's response, particularly DOD's investigation into CBW exposures. In others, such as medical treatment provided to Gulf War veterans, it fell short of the mark.

Because its charter did not allow the committee to conduct original research, it could not follow up with Gulf War veterans 6 months or a year after they received treatment from DOD and VA. Therefore, the PAC may have visited some centers and talked to DOD doctors and VA doctors, but they couldn't find out for sure how effective the treatment Gulf War veterans received.

The American Legion commends the PAC and its staff for their professionalism and dedication to helping Gulf War veterans receive the care and answers that they deserve.

Thank you, Mr. Chairman. That concludes my testimony.
 [The prepared statement of Mr. Puglisi appears on p. 372.]
 The CHAIRMAN. Thank you, sir. Mr. Violante.

STATEMENT OF JOSEPH A. VIOLANTE

Mr. VIOLANTE. Mr. Chairman, Members of the Committee, on behalf of the more than one million members of the Disabled American Veterans and its auxiliary, I wish to express our deep appreciation for this opportunity to provide our assessment regarding Gulf War illness.

The issue of Gulf War illness is a serious problem, made more difficult because of its complexity, the lack of scientific/medical evidence, the failure to maintain complete military and medical records, the failure of the Department of Defense to come forward with critical evidence establishing the possible exposure to chemical agents by US troops, and the conflicting reports and conclusions reached by various scientific and medical commissions and individuals.

These are not new dynamics for veterans. However, the fact that there are still so many unanswered questions and so many conflicting medical opinions only serves to exacerbate the situation.

Mr. Chairman, the plight of Persian Gulf veterans suffering from undiagnosed illnesses continues to be one of our foremost concerns. Of the 11,257 environmental hazard claims considered by the VA, slightly less than 1,400 have been granted service connection, and only 620 or five percent have been granted service connection for undiagnosed illnesses.

DAV continues to suggest that the presumptive period be left open-ended until the scientific/medical community determines the cause or causes of these ailments. We believe that the passage of time has demonstrated the soundness of our position.

We caution this committee, however, not to take legislative action that would trigger pay-go provisions of the Budget Enforcement Act. In fact, Congress should exempt veterans benefits and services from the pay-go provisions.

Mr. Chairman, the most frustrating aspect of Gulf War illness is that 6 years after the end of the war, we are still unable to answer the question about what is causing these undiagnosed illnesses. Unfortunately, the report by the Presidential Advisory Committee on Gulf War Veterans' Illnesses does not provide any concrete answers to this question.

While the PAC has stated that veterans clearly have service-connected illnesses, they conclude that current scientific evidence does not demonstrate a causal connection between so-called Persian Gulf illness and the environmental risk factors that veterans were exposed to in the Persian Gulf.

The PAC report focuses on stress as a likely contributing factor to the broad range of psychological and physiological illnesses currently being reported by these veterans. It is noted that based on decades of clinical observation, physicians recognize that many physical and psychological diagnosis are the consequences of stress. The PAC concluded that, "Stress can be contributed to a broad range of physiological and psychological illnesses. Stress is likely to

be an important contributing factor to the broad range of illnesses currently being reported by Gulf War veterans."

We note with great interest the statement that decades of clinical observations demonstrate a causal connection between stress and many physical and psychological diagnosis. For decades, the VA has denied any connection between service-connected post traumatic stress disorder and most physical or psychological disabilities. Veterans have routinely been unsuccessful in attempts to obtain service connection for other disabilities secondary to post traumatic stress disorder.

Should Congress decide to give VA the authority to provide benefits or services to children of Persian Gulf veterans, as suggested by the PAC, because of the adverse health effects resulting from their parent's service experience, current VA programs and benefits will have to be cut to satisfy these new services. Therefore, we call upon the Committee to assist us in returning the excess Gardner Funds to VA for use by the VA to implement or enhance programs and/or benefits.

In conclusion, let me state that the PAC report has offered important suggestions and recommendations with regards to dealing with the current problems in health care and outreach needs of Persian Gulf veterans. Unfortunately, we are not provided with any concrete answers as to what is causing their illnesses.

Mr. Chairman, we call upon this committee, the entire Congress, VA, DOD, Health and Human Services, and all other departments and agencies involved in Gulf War illness to continue to seek answers to explain the mysteries surrounding the illnesses suffered by Persian Gulf veterans.

This concludes my statement. I would be happy to answer any questions.

[The prepared statement of Mr. Violante appears on p. 380.]

The CHAIRMAN. Thank you, sir. Mr. Ford.

STATEMENT OF JEFFREY S. FORD

Mr. FORD. Thank you, Mr. Chairman, and Members of the Committee for allowing me to testify today on behalf of the National Gulf War Resource Center.

We found that the PAC concluded, and I quote, "Most DOD and VA outreach efforts concentrate on publicizing the clinical evaluation programs, then referring participants to them—these efforts do not fully educate veterans or sufficiently build their trust that the Government's efforts to help them are comprehensive."

They have "not established clear pathways for veterans to provide feedback about clinical programs and/or concerns regarding exposures; nor have they canvassed Gulf War veterans' community regarding better methods of communication. It appears the only way in which a veteran can provide feedback would be through contact with the clinical personnel at local VA medical centers or military hospitals. This however does not appear to be a likely route for transmitting concerns to decision makers."

We veterans can assure you that this has been a serious problem from the start. In November of 1995, the PAC began visiting VA and DOD medical facilities. The facilities that they visited by their very nature are some of the better facilities treating Persian Gulf

illnesses, and does not reflect a true representation of the level of care nationwide. Yet the PAC found serious problems even at these facilities.

At several referral centers, it was noticed that "the knowledge of level staff not specifically assigned to the registry or CCEP at both VA and DOD medical facilities was problematic. For example, the existence of the CCEP was largely unknown among staff at the VA facilities we visited."

They further quoted, "clinical staff not directly involved in the VA's registry and DOD's CCEP are not well informed about the programs." Also, "at the time of the Committee's site visits, some staff at VA medical facilities complained they were receiving less information about the program from VA central office than they felt needed."

The Committee fails to mention that many VA Persian Gulf registry program coordinators also conduct Agent Orange, as well as compensation and pension appointments and exams, overburdening the often single individual. Therefore, Gulf War registry participants receive least consideration.

The PAC says, "The committee heard public comment at each meeting, citing insensitive attitudes on the part of the staff at both DOD and VA medical facilities."

"Frequently, these reports by veterans and their families centered on a dismissive or cynical approach to the veterans' problems. The message received was that problems were not real or all in your head. Veterans who sought care after the Gulf War, but before the establishment of the Registry and CCEP appeared to suffer most from this treatment."

We veterans wish to know where are those veterans now, and how can the VA hope to repair this breach of trust and encourage these veterans to return to the system.

Then I found this most interesting comment. "Most facilities did not designate a separate clinic for phase I evaluations, seeking to mainstream participants as much as possible and reduce the possibility of symptom sharing." We wonder if the PAC assumes that over 100,000 ill Gulf War veterans from across the United States and around the world have shared their symptoms amongst themselves to conspire against the VA.

From the first small group of Indiana veterans who came forward in 1992, a group that was dismissed as malingers, the symptoms reported have not changed. This seems to negate claims of so-called symptom sharing. This Government's trend of discounting reports from our own soldiers in favor of reports from Iraqi deserters, foreign governments, UN officials, and bureaucrats is disturbing.

The PAC further found that "VA has no policies in place to systematically address the concerns of Gulf War veterans regarding reproductive health." "Both the Registry and CCEP programs are treatment programs, not research protocols. But the data have been used to generate research hypothesis." "This committee and others have judged the protocol to be an excellent tool for diagnosing illness", but we veterans must question then what is considered to be a useful tool for dealing with undiagnosable illnesses?

Yet the PAC asserts that "DOD and VA have implemented innovative programs to help veterans cope with combat related stress." Then the "Committee found that overall high-quality healthcare is [being] provided."

We find that since the majority of studies funded and nearly half of the studies completed to date were stress related, it is not surprising the Committee found stress to be an important contributing factor. It is also the subject area in which DOD and VA have provided the most information.

We are also concerned about the FDA waiver, the process currently being used permitting DOD to evade legal safety requirements.

"The Committee also concluded that the unit locator has not proved to be a valuable tool for investigating exposure incidents." Therefore, we believed it should not be used to determine service connection based on a veteran's exposure at supposed unit locations.

According to the PAC, "DOD has conducted a superficial investigation of possible chemical warfare agent exposures that is unlikely to provide any credible answers to veterans and public questions." "To ensure credibility and thoroughness, further investigation of possible chemical and biological warfare agents exposures during the Gulf War should be conducted by a group independent of the DOD." Yet the Pentagon will continue to be the lead investigative agency. We question the Committee's ability to provide credible answers, and in part because their report relies too heavily on information from agencies whose efforts have been criticized by the PAC as being superficial and inadequate.

It also operates using consensus management. It may be a useful tool for looking at issues surrounding quality of VA care, but inappropriate for evaluating scientific research.

Therefore, we request that any further investigation be conducted independent of any government agency and that all records and evidence the PAC now holds be turned over to Congress for proper and open investigation.

They also say that "available data is sparse." "Generalizable conclusions about the nature and extent of illnesses will come only from population-based epidemiological studies that will not be completed until well after the Committee disbands."

Their mission, and when I say they, the DOD, DHHS, and VA, to provide all veterans a complete health range of services necessary for medical problems that might be related to their deployment. We do not believe this has been done yet.

Six years after the war, we still have no broad-based epidemiological data on the nature of the illnesses suffered by the veterans and their families. Mr. Chairman, it is now 6 years since the Persian Gulf War. We now know that veterans were exposed to a number of hazardous compounds which alone or in combination may be causing illnesses similar to those being reported. The Government still does not accept that these exposures may have resulted in our illnesses. We are still debating whether or not the Pentagon is involved in a coverup. It's time to move on.

Time to presume that these exposures occurred. Time to initiate appropriate broad-based epidemiological studies for our veter-

ans and their families. Time to enlist the support of independent scientists and researchers concerned about curing disease, not those who are more concerned about protecting their agency's bureaucratic interests.

In conclusion, not only do I represent thousands of Gulf War veterans here today, I must note that I served with the 307th Engineer Battalion, and participated in the entire destruction of the Khamisiyah Weapons Depot facility in Iraq, and personally delivered and set the demolitions at the pit area containing tons of mustard agent.

Finally, it is time that we stop investigating the investigation and move on to provide quality care to our veterans, and a review of the safety measures we implement to protect those still on active duty.

Mr. Chairman, I thank you.

[The prepared statement of Mr. Ford appears on p. 387.]

The CHAIRMAN. Thank you. Thank you, gentlemen. Mr. Evans

Mr. EVANS. No questions.

The CHAIRMAN. No questions. Dr. Cooksey.

Dr. COOKSEY. So you were involved in the destruction of the weapons. Is that correct?

Mr. FORD. I was in Khamisiyah from March 3 until March 15 of 1991. I hauled most of the demolition supplies for the entire operation.

Dr. COOKSEY. You were aware of what you were destroying obviously.

Mr. FORD. We were aware that we were denying Iraqi—the Iraqi forces munitions. We had no knowledge of any chemicals being present at Khamisiyah.

Dr. COOKSEY. When did your symptoms begin?

Mr. FORD. I am currently not expressing or showing any signs and symptoms of what we now know to be Gulf War illnesses.

Dr. COOKSEY. Were either of you there?

Mr. VIOLANTE. I was not.

Mr. PUGLISI. I was in the Gulf War, yes, sir. I wasn't up around Khamisiyah. I was with the second Marine division in Saudi Arabia and Kuwait.

Dr. COOKSEY. Are you still in the military?

Mr. FORD. No, sir. I am not. I serve as the Executive Director of the National Gulf War Resource Center, which is a coalition of over two dozen grass roots Gulf War veterans' organizations from around the country as well as Britain.

Dr. COOKSEY. What is your profession?

Mr. FORD. This is my profession, sir.

Dr. COOKSEY. Okay. I am impressed with your testimony. Very significant.

Thank you, Mr. Chairman.

The CHAIRMAN. Dr. Snyder? Mrs. Chenoweth? Mr. Bachus? Mr. Bilirakis?

Mr. BILIRAKIS. Mr. Chairman, I have no questions. But I just wanted to point out I am always very proud to point out that many of the Department of Veterans Affairs people stayed for the full hearing. So they are here to listen to these gentlemen, as well as to the three Gulf vets who are coming forward afterwards. I

thought I would point that out, because I think it's just very good of them to do that. Thank you, sir.

The CHAIRMAN. Thank you, Mike.

Gentlemen, thank you very much.

If we can have the final panel, please. We have three Persian Gulf War veterans, Mr. David Smith, Mr. Carl Wickline, and Mr. Derek Davis.

Mr. Smith, since your name is first on the list, we'll start with you, please. If you would keep your remarks to 5 minutes, your entire statement will be printed in the record. Thank you, sir.

STATEMENTS OF DAVID TROY SMITH, PERSIAN GULF WAR VETERAN; CARL E. WICKLINE, PERSIAN GULF WAR VETERAN; AND DEREK E. DAVIS, PERSIAN GULF WAR VETERAN

STATEMENT OF DAVID TROY SMITH

Mr. SMITH. Good afternoon, Honorable Chairman and Committee Members. Thank you for the opportunity to testify. I am David Troy Smith, a former United States Marine NCO who honorably discharged July 12, 1991, after 9 years of service. This ended with the Ninth Communications Battalion, First Surveillance, Reconnaissance, Intelligence Group in Operations Desert Shield and Storm from August 10, 1990, to April of 1991.

Prior to deployment in Persian Gulf, I participated in the Marine Corps athletic program from 1986 through 1990. During this period I earned from the Department of Defense four certificates of achievement for athletic endeavors, and six all marine certificates for wrestling, power lifting, and track and field, including competition at four United States national championships and five military national championships.

I maintained unit integrity with microwave communications as a senior NCO with a secret security clearance. My career began as a marine series honor graduate. With these accomplishments behind me, I felt my personal mission in the United States Marine Corps was complete. I secured a job as a manager of a World Gym in New Jersey, where I won the state power lifting championship for the 242 pound class.

After moving to Idaho, I secured a job as woodshop supervisor for an international arcade game distributor, all the time trying not to recognize the medical problems, not wanting them to interfere with my objectives, that of having a wife and children, whose mother did not need to work.

Now I sit before this Committee, a 32-year old father of two, VFW service officer and Idaho State commander for the Desert Storm Justice Foundation. I am officially bankrupt, totally disabled by the Social Security Administration. I am able to receive vocational rehabilitation from Social Security or the Department of Veterans Affairs, and until recently, had no sign of compensation from the Department of Veterans Affairs.

My hope is to bring to light the suffering that many of our United States veterans confront daily and that something as powerful as this committee can affect the necessary changes to ensure aggressive treatment and compensation for all ill veterans.

The testimony I am giving is a brief history of the past 5 years of my medical battle with the VA. Some significant people are Senator Kempthorne's office, Congresswoman Chenoweth, the American Legion and its Gulf War Task Force, especially Mr. Carroll Williams, for bringing the problems to the attention of the VA Central Office in Washington, DC, who now are aware of the problems and have worked quickly to resolve the situation.

Prior to my deployment to the Persian Gulf, I was weighted on a freight scale to verify that my weight was 263 pounds. However, within 2 weeks of the ground war, I developed high fever, diarrhea, severe weight loss, which ended in a 24-hour period loss of consciousness. When I awoke in my sleeping bag, I was face down soaking wet, and I had defecated on myself.

This incident came within 72 hours of being forced to receive injections from the Battalion Aid Station where they tried to force me to sign a form that stated, "By signing this form, you relieve the United States Government of any possible side effects of this medication."

When I departed the Persian Gulf in 1991, the bowel problem was sporadic and my weight was returning to normal. I returned to the United States and began processing for discharge. However, this was delayed when I was placed on medical hold for stomach problems. During the internal medicine consult at Camp Pendleton, CA, it was determined that it would take 3 months longer for the workup.

To me, this did not seem something that marines should do. This was conveyed to the internal medicine doctor who assured me that if I discharged, it would be noted on my final physical and in my medical records. I was assured that the VA would take care of my problems so long as it was documented. I agreed to go to the VA upon discharge and was released because this problem was not life threatening, and my weight had returned to a point of 255 pounds.

I returned to my unit, and finished my discharge paperwork, and was told that my medical records would be sought by the VA once I went for treatment. Having been discharged in July of 1991, I was eager to get on with life. Although my medical problems became bothersome, I felt as a Marine, the headaches and diarrhea were trivial problems to bother a doctor for.

When I was advised by an American Legion post commander and Vietnam veteran that the medical problems needed to be documented by the VA, a New Jersey State service officer arranged for my first examination with the medical system at East Orange, NJ, in September of 1991, less than 3 months after my discharge from the Gulf.

When I arrived for my visit to the doctor, it turned out to be a compensation and pension exam. During my exam, the doctor found no reason for the headaches, but recommended I see an ophthalmologist as part of the exam, who determined this was the cause of my headaches, and a prescription for glasses were issued.

In September of 1992, I sought treatment at a Walla Walla VA Medical Center because at this time, the bowel problem had turned into explosive diarrhea that manifested without warning and the headaches were severe. The problems continued, and I was assigned a primary physician. From 1992 through July of 1994, I un-

derwent numerous consultations with mental health, opthamology, neurology, and gastro-intestinal, all with varying diagnoses. Yet none were followed by my primary care physician.

During this time, I also underwent two compensation and pension examinations with noted varying problems. Results were received in 1994 of the Persian Gulf Registry physical, which stated, "Chronic diarrhea etiology unknown and chronic joint pain despite lack of findings." This was the last I heard from the medical side, yet mental health encouraged me to attend post traumatic group therapy. I did not see the necessity for therapy because flashbacks, bad dreams and problem adjusting to civilized world were expected.

I collapsed, in September of 1994, I collapsed on my kitchen floor too weak and from pain and had defecated on myself again. My wife became concerned. Through the intervention of Senator Kempthorne's office, I was given a medical appointment within 24 hours at Walla Walla VA Hospital for referral to the Persian Gulf Workup Center. Once my referral was in process, I became concerned as to what was expected and how would I support my wife and two children. Upon contacting the Persian Gulf coordinator at Walla Walla Hospital, her response was, I can try applying for welfare, go to my family or my friends or my church.

I then contacted my referring nurse. She also did not know anything. I was given a number to contact the program director's office in West LA. The information he conveyed was quite disturbing.

Upon arrival to West LA, I immediately became aware of what a teaching hospital was about. The problems I was forced to deal with during my actual 39 day stay were numerous. A good portion of the stay I maintained a journal to track exactly what was happening.

My roommate was a 30-year retired Army sergeant major who was dying of cancer. He instilled a very stern warning. Watch the VA for PTSD therapy and any kind of narcotic painkillers.

In December 2, 1994, I discharged with seven noted medical problems and nine medications, ranging from morphine to prozac. The last thing I did was go to records and sign the release of information for a complete copy of all medical records once they became available. Again, Senator Kempthorne was involved to get the records transferred and my copy of the records, which now carried a stamp that stated, "These documents or records or information contained therein are deemed confidential and privileged information with fines up to \$20,000 for violations."

Would you like me to wrap it up?

The CHAIRMAN. If you would, sir. We appreciate your willingness to wait all this time. We will you allow you to go on, if you could kind of wrap it up.

Mr. SMITH. I only have one more page, sir.

Upon arrival at Walla Walla, December 8, 1994, we had anticipated some problems, only arriving with a single discharge and a primary care physician who did not think I was sick. I was met by a nurse who told me the only thing that could be done was to schedule an appointment for 30 days from now, January 8, 1995.

I then inquired about the medications which were to expire January 1, 1995, and was assured if I called the prescriptions one

week prior, they would be refilled. What she did not say was this was at doctor's discretion.

When I returned on January 8, to see my primary care physician, my records had not arrived from West LA, and he did not agree with the findings of the West Los Angeles hospital. This was the reason for not renewing the medications. The problem with stopping my medication for morphine without warning, was I had been on this narcotic for 2 months straight.

I called Dr. Ronald Hamm for assistance in processing my medical records because treatment would not be continued until my complete medical file was present. He assured me the records were en route. The only thing he could offer me was a detoxification center in West Los Angeles, CA.

February 5, 1995, is the last time I saw my primary care physician, who felt there was nothing else he could do for me. Mental health continued to offer treatment. I self-admitted October 2, 1995. During this time, I received group therapy once a day and no other treatment, even though more workups were ordered.

The last time I received anything from Walla Walla Hospital, was a letter telling me that I was not eligible for treatment until service connection for medical problems was established. I tried to seek treatment at other hospitals, but with the same result. No treatment until service connection is established.

A private dermatologist wrote a letter stating that diagnosis of a biopsy on my forehead that swelled out and it prompted a referral to infectious disease on January 16 of this year by a doctor I have not been examined by for over 2 years.

In closing, the chance to present my story before this committee is an honor and a privilege. Yet I have considerable concern that it takes a hearing by this House Committee to shed light on the problems that thousands of veterans are encountering daily after service to this country, much like myself, who clearly needed help to acquire medical attention. This, from a system that was established as Abraham Lincoln stated, "To care for him who shall have borne the battle, and for his widow and his orphan."

Thank you for the opportunity to appear before this Committee. [The prepared statement of Mr. Smith appears on p. 397.]

The CHAIRMAN. Thank you, Mr. Smith. We'll get back to you in a minute.

Mr. Wickline, if you would pull a mike over just as close as possible, we're ready to hear your statement.

STATEMENT OF CARL E. WICKLINE

Mr. WICKLINE. Thank you, Mr. Chairman. My name is Carl Wickline. I am a Gulf War veteran with numerous physical symptoms which I believe to be a direct result of exposures encountered while in service in Saudi Arabia and Kuwait.

I served in the United States Marine Corps from November 1988, to August 1993, during which time I was deployed to Saudi Arabia with the Third Light Armored Infantry Battalion, in September 1990, for Operations Desert Shield and Operation Desert Storm. I remained with this unit until I was honorably discharged from the Marine Corps in August, 1993.

While in the theater of operations within Southwest Asia, our unit provided tactical mobile ground combat support within the northeast area of Saudi Arabia, moving north from King Fahd International Airport to Jubayl, the Chicken Ranch, Manifa Bay, First Marine Division Support activity, Khaffi and tactical support positions along the southern border of Kuwait.

During operations Desert Shield and Desert Storm, there were prolonged exposures to burning oil well fires, smoke, ash, minefields, which contained gas mines, artillery fire, enemy small arms fire, destroyed armored vehicles, spent ordinance air and artillery, dead bodies, human and animal, and enemy bunkers which we destroyed with explosives.

Military operations within Kuwait ranged as far north as the Kuwait International Airport, often in blackout conditions due to the thick black smoke which blocked all light at times.

Multiple symptoms began to become noticeable shortly after returning to the United States. Symptoms have included the following. Recurring severe headaches, chronic fatigue, recurring neuromuscular back pain, short-term memory loss, lapses in concentration, severe rash, depression which medication has not successfully treated, night sweats, insomnia, severe gastro-intestinal problems, blurred vision, photosensitivity, bleeding gums, immune system inefficiency, and multiple chemical sensitivities.

Shortly after my return from the Gulf in 1991, my wife and I began to notice symptoms which we felt may have been the result of my service in the Gulf. As I sought medical treatment through the military prior to my discharge, I encountered several problems. First, although I was ill, doctors found no explanation for the symptoms.

Second, I was refused treatment by at least one internal medicine specialist, due to the fact that he could not diagnose the problem and that medications did not alleviate the symptoms and often made the symptoms worse.

Third, I was told by several medical professionals within the military that they understood I was sick, but I would have to learn to live with the symptoms.

It was suggested to me that I was crazy or at least mentally unbalanced. Also, when I began treatment with a doctor, a civilian doctor in early 1993, I was threatened by military medical officers and personnel with court marshal, due to the fact that I had gone over their heads.

I would like to make three side notes before I talk about my experiences with the VA medical side. First of all, note that the Gulf War illness as well as hepatitis contracted in the Gulf were annotated on my discharge physical prior to separation from service. Second, it's also interesting to note that I applied for reenlistment in the Marine Corps in November, 1993, and was denied due to medical condition. Third, I have been denied healthcare insurance on two occasions since my discharge due to Gulf War syndrome, specifically.

My first contact with the VA came shortly after being discharged from service. In September 1993, I filed a claim which cited both active duty medical records and discharge physical as support for this syndrome which has been so hard to diagnose and treat. Ini-

tially the complaints for these symptoms were overlooked, while I was referred to mental health for evaluation and treatment for depression.

Several attempts were made to go through the out-patient clinic at the Lexington, Kentucky VA hospital. On each occasion I came in complaining of the same symptoms, with similar results each time. Attempts were made to alleviate the symptoms with medications. Most of these attempts were unsuccessful.

Basic blood tests have been done, but any actual research or in-depth testing has been overlooked. Neurological workup has been done. However, the results were inconclusive, and no further testing has been done.

It seems that I end up in the same place each time I attempt to contact the VA concerning my illness. Mental health must be the deadend for all cases which the VA has no knowledge or interest in treating. I have been prescribed several medications, none of which have had any effect other than to increase fatigue and gastro-intestinal problems.

My most recent visit to the VA was the 16th of December, 1996, in Oklahoma City. At this meeting, I provided the doctor with a complete list of symptoms, as well as test results from several professional medical labs, along with diagnosis from a doctor in Santa Ana, CA.

I was told by this doctor that he was not interested in seeing any of the documentation which I had provided for him. I was told he did not have time to look at my paperwork and that I was obviously suffering from depression and possibly hypertension, after which I was prescribed an anti-depressant and a stomach medication. A return appointment and basic blood work were requested and have been scheduled.

Once again I find myself in the same spot in which I always seem to find myself. The issues have once again been side-stepped and I still suffer from the same symptoms which I have seen no honest attempts towards diagnosis or treatment. Thank you.

[The prepared statement of Mr. Wickline appears on p. 412.]

The CHAIRMAN. Thank you, sir. Mr. Davis.

STATEMENT OF DEREK E. DAVIS

Mr. DAVIS. Mr. Chairman and Members of the Committee, my name is Derek Davis. As a veteran of the Persian Gulf War, I appreciate the opportunity to testify today. My service in the Gulf was as a commander of the Army National Guard's 276th Military Police Company. My company was deployed to the Gulf in February of 1991, after approximately a month medical screening and final training at Fort Meade, Maryland.

Our pre-deployment medical screening was very thorough, much more so than at the separation after returning from the Gulf. Several men did not deploy because of health problems that were uncovered. Those who left from Saudi were in excellent health and top physical shape. Ours was a cracker-jack company which had served several overseas missions with distinction, to include Panama and Hurricane Hugo.

My company's mission in Saudi Arabia was to provide security for a large ammunition supply point in a desert area approximately

10 miles from Khobar. The company area where my company bunked and took our meals was just downhill from a munitions storage area. Within the first few weeks, first weeks after getting in-country in February, I became aware that several of my men were becoming ill, with difficulty in breathing, runny eyes, and diarrhea. Several men were hospitalized.

Because of suspicions that living and working full-time in close proximity to the munitions storage area had something to do with their illness, these illnesses, I requested a change in the location of our camp area and recommended the establishment of rotating duty shifts to cover the security requirements. These recommendations were accepted.

I also asked headquarters to conduct a survey of the site to see what was wrong. An environmental assessment was conducted on May 15, 1991. I received a copy of a memorandum which I asked to be placed in the record, which states that this site, ASP Quarry, and I quote, "has now been identified as containing significant respiratory hazards, both in the form of toxic gases and various airborne particulates."

The memo from a headquarters physician made reference to protective masks which had been found successful in filtering out particulates, and stated, "It is vital that a protective mask of the above type be made available to every soldier who will be on duty in the ASP Quarry." Many of my men were alarmed by the issuance of these masks, but we wore them while on security rotations. My request to my brigade commander for a copy of this environmental report received no response.

I do not have personal knowledge of what we may have been exposed to as ASP Quarry, but in attending a very high level meeting at a later date, I heard a conversation among high ranking officers that indicated that unconventional, highly classified ordnance was among the ordnance stored there.

My company's experience in Saudi also included numerous warnings of SCUD launches. After many false alarms, my men had become more relaxed about the loud warnings, SCUD launch, but we were less than a mile from the SCUD that killed 23 men. I was relatively lucky. I only sustained a concussion in seeking cover from the clearly visible incoming rocket. The injury led to a total loss of hearing in my right ear.

I am proud of my service in Saudi, and of the Bronze Star and Army Commendation Medal I received for that service. I am convinced, however, that something other than my hearing loss happened to me and to numerous of my men in the Persian Gulf. I began to have many problems almost as soon as I returned to the States. I couldn't pinpoint a cause, but I had difficulty sleeping, difficulty in breathing, and was constantly fatigued, had joint pain, memory loss, and stomach problems. I had had none of these problems before serving in Saudi.

I had been a relatively high achiever before my service. I completed college studies, earning a BA degree from the University of Maryland, College Park. I was unprepared, however, to deal with the health problems I experienced after returning from Saudi Arabia. I regret that I turned to alcohol to mask my pain. Only after

serious family problems did I stop drinking, and I have been active in AA since 1993.

My health problems did not improve. Finally, with the establishment of the VA Registry program several years later, I turned to VA. I was evaluated extensively by the VA Medical Center in Washington, DC, and later by Walter Reed Army Medical Center. These evaluations, which included extensive testing during a period of VA hospitalization, led to my being diagnosed as suffering from sleep apnea, fibromyalgia, degenerative joint disease, and PTSD.

I especially want to acknowledge that I have gotten a lot of help from VA Medical Center's PTSD program, and I have a very high regard for the clinical staff. They have helped me cope with what I am going through. I continue to be under treatment from VA and receive medication. My other medical problems still give me a lot of trouble though. I have almost come to accept that if VA and Walter Reed have been unable to resolve these problems, that they are not likely to get better, and I will have to learn to live with them.

As one who served in war for this country, and I believe became sick as a result, I do expect that those who work to assist veterans will be empathetic, and give me some special consideration. Many VA clinicians and staff have done just that, and I do want to acknowledge that. For example, when I have had problems there, the VA patient-advocate at the Washington VA Medical Center has jumped right on it and resolved them, but there have been frustrations.

If it is not possible to cure my problems, my health problems, I believe the Government should acknowledge that they are due to military service and provide appropriate compensation benefits and vocational rehabilitation, because it is increasingly difficult with my joint pain to work at a job that requires me to stand all day. Unfortunately, I have had a lot of problems getting favorable actions of any type on my claim for service-connection, which I first filed years ago. Even my hearing loss, which is documented in my military medical records in 1991, has yet to be adjudicated as service-connected.

While the many physicians that have treated or evaluated me have generally been concerned, a few seemed like they were just going through the motions. In one particularly upsetting case, a psychologist at Walter Reed wrote a statement in my medical records to the effect that I might be faking these symptoms.

It is also unsettling to have to wait about 4 months to undergo VA testing for a severe sleep disorder. This negative experience I have had as a patient, such as long waits to discuss my case with a physician, an error in my medication, and being billed in error for care that was supposed to be free. It may seem trivial, but after years of battling these health problems, even small issues become large.

In closing, let me say that I am testifying not just for myself, but for the many others who are also hurting. Although I am not the man I was when I left for Saudi Arabia, many of my troops are still looking to me to take care of them. I hope this Committee will help me help them. Thank you.

[The prepared statement of Mr. Davis, with attachment, appears on p. 403.]

The CHAIRMAN. Thank you, Mr. Davis. Thank all of you. Your testimonies will be very helpful. Mr. Evans.

Mr. EVANS. Thank you, Mr. Chairman. I think it's been very important to have the human carnage of this war come before us today. I say that because I know it's not real easy for you guys to bring forth these problems. You are not malingerers. You are hard workers. You had excellent service records going over to the Gulf. I appreciate that very much. So I appreciate you being with us here today.

Mr. Davis, you are discharged now from the National Guard at this point?

Mr. DAVIS. That's correct.

Mr. EVANS. This is a locally based command?

Mr. DAVIS. Yes. It's locally based.

Mr. EVANS. Have you been able to keep in touch with other members that were with you in Saudi Arabia?

Mr. DAVIS. Yes. I talk to them very frequently. In fact, some, a few of them are in the PTSD program with me at VA Medical Hospital here in Washington, DC. I get a lot of calls from my troops who served with me in the Gulf. They let me know how they are doing, their families are doing. Just running into them from time to time on the streets.

Mr. EVANS. How are they doing?

Mr. DAVIS. A lot of them are sick. A lot of them are ill. A lot of them are confused. One of my troops told me he had a parasite in his blood they found up at VA. Another one had a rash, butterfly rash on the back of his back. One my female troops I happened to run into had this rash all over her body. One of my troops shortly, and I guess within a week after returning from the Gulf died. They said it was heart, respiratory failure. That's Bernard Griffin, who we established an American Legion post 276 in his name. Another one of my troops, we called him Radar. I can't recall his name right now, forgive me for that. He's had testicle cancer. He never smoked or drank. He was one of those guys, if you watched MASH, he was like a radar. Just one of those nice humble guys. So there has been some illness.

Mr. EVANS. Has there been any follow-up by the Department of Defense in investigating that specific unit, given the fact that you might have been exposed, I take it, to some kind of chemicals out of that ammo bunker? Was there any follow-up at all by the Department of Defense after you shifted to rotating?

Mr. DAVIS. No. There is document. I hope you all have a copy of that. But the document that they did the environmental study out there, in which they brought out special masks for us to wear, for my troops to wear, everyone of them showed their document to, has always just handed it back to me. I do know a lot of people that got sick and special masks were provided. Nobody from DOD has called or contacted me or anybody in my unit that I know of.

(See p. 409.)

Mr. EVANS. All right. Let me ask everybody on the panel. Do you have any specific recommendations on how the VA can improve healthcare programs for Persian Gulf veterans?

Mr. SMITH. I would say first that the communication between hospitals, even within the hospitals needs to be addressed. If I can talk, I'm from Idaho. I flew out here to testify. If I can talk to somebody on the east coast with the Internet on my computer, there's no reason that the VA hospital shouldn't be able to talk from the travel clerk to the admissions clerk. I have run into that many times. That would be my biggest suggestion, communications.

Mr. EVANS. Anybody else?

Mr. WICKLINE. I think that I'm going to refer to this Persian Gulf War Illness fact sheet that I picked up when I came in this afternoon. So far, I haven't been offered all of these things through the VA. Possibly if everything on here was offered to us, then perhaps some things might be getting done, to put it quite bluntly.

Mr. DAVIS. I am sorry. Could you repeat your question again?

Mr. EVANS. What recommendations would you give to us to improve VA health care for Persian Gulf veterans?

Mr. DAVIS. I think sensitivity is one. Maybe some, I guess what we call in our civilian world, staff development. Maybe some concern, people concerned in the sensitivity to the troops or to their patients that come up there that have had these medical problems I think would help a lot.

I find, and even for myself, one of the main things and I have expressed that with some people here, I would rather not call their names because I don't know whether they would want their names called, but just somebody to listen to the nature of their problems and then getting on with it helps a lot. So I say communication and sensitivity.

Mr. EVANS. Thank you, Mr. Chairman.

The CHAIRMAN. Dr. Cooksey.

Dr. COOKSEY. Thank you, Mr. Chairman. First, I want to thank you veterans of this Gulf War for coming here, first for serving, and then for coming here today and expressing your symptoms. That means a lot to me, and it lends a lot of credibility to your complaints.

I can assure you that as a new member of this committee, we will work very hard to find out what the problem is. First, we have got to find the cause of it. Then we can do something about the treatment.

In the meantime, I can assure you that for myself, and I feel that the other members of the committee, we will work hard to make sure that the Veterans Hospital responds as best they can to your health care needs, because that is what we are all about.

We do need to continue to have a strong military. We will probably face more problems like this in future wars. It will be the youth, as always, that fight the war. It's never a grey-headed old politician. They are the ones that get us into the war. The youth fights it. But we need to look out for you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, sir. Dr. Snyder? Mrs. Chenoweth?

Mrs. CHENOWETH. Mr. Chairman, I want to thank you, this being the 11th hearing on this particular subject. I really appreciate your dedication to solving the problems. I appreciate the fact that you ushered through the House and to passage into final law, Public

Law 104, 262, which authorized the Department of Veterans Affairs to give priority health care to our veterans. That is part of the question that I was asking about where is the threshold where they will determine that a veteran should receive priority care.

So again, Mr. Chairman, thank you very much. I would like to work with the Committee on that threshold.

The CHAIRMAN. Thank you. We look forward to it.

Mrs. CHENOWETH. David Smith, thank you for coming, and your wife Debbie, at great expense I know. But it's something else you are doing for the country. I really really appreciate you.

You talked about your physical condition before you went into Desert Storm. Did you by chance remember having blood drawn before you went into the service, I mean before you were in active duty at Desert Storm?

Mr. SMITH. None, no, as far as I know. I didn't have any. I rarely saw a doctor during my 9 years of service.

Mrs. CHENOWETH. I asked that because the VA officials seemed to think that was important. I didn't know whether it was something that was normally done.

Mr. SMITH. I was the first jump team out of my unit out of the ninth battalion. I said I was in Saudi on the 10th of August, not much time for anything.

Mrs. CHENOWETH. And you were right on the front lines, weren't you?

Mr. SMITH. I worked my way to the front line. Yes, ma'am.

Mrs. CHENOWETH. Yes. Has your illness changed your quality of life?

Mr. SMITH. The quality of my life was affected all the way from being able to eat to my bedroom with my wife. I have been told by the VA not to have unprotected sex with my wife. We have been married 4 years.

Mrs. CHENOWETH. David, what is the prognosis of your illness?

Mr. SMITH. I have a list of medical conditions. I have been told my condition was considered terminal by a VA doctor. I have that letter, if anyone would like to see it. Currently I receive 60 percent disability rating, dating back to the date of discharge. I received that on Friday, February 7, on the day before I left to come to this committee, after 5 years and 7 months of an open claim with no answer. They found clear and unmistakable errors in the rating decisions of 1992 and 1994. That's what the Phoenix office found. After a recommendation from Christine Moffit of the Central Office here in Washington, DC. This took you yourself and Senator Kempthorne and the American Legion Task Force to get this done.

Mrs. CHENOWETH. David, were part of those records that the new reassessment was based on, were those part of the records that were received with the stamp that if you give this to anybody, you might get a \$20,000 fine?

Mr. SMITH. Yes, ma'am. All those were submitted.

Mrs. CHENOWETH. Were your medical records obtained easily by the VA? You have testified somewhat to that.

Mr. SMITH. As far as I know, my records were not obtained by the VA. I have a letter from the Director of the Reserve Records Center to the commanding officer of the Ninth Communication Battalion that I pulled from my service record that states that my

medical records never made it to the Reserve facility. That was the problem with my service-connected disabilities. Nobody could prove anything.

Mrs. CHENOWETH. Are you aware of other veterans in Idaho or around the Lewiston area where you live who have run into these same bureaucratic entanglements?

Mr. SMITH. Actually I have helped quite a few veterans try to receive treatment through the Department of Veterans Affairs from the Idaho area, over 20, that are not able to receive, are having to fight the Walla Walla Hospital for treatment.

Mrs. CHENOWETH. David, did you sign a waiver of informed consent prior to receiving the inoculations for anthrax and botulism?

Mr. SMITH. No. I did not. I received the shots and I was threatened with court marshal by the commanding officer of the medical BAS if I did not. I was raising a commotion, and I couldn't understand why that stamp was on the top of the form to sign. So I raised a commotion, and I was—I took the shots. I wouldn't have to sign the form.

Mrs. CHENOWETH. How long, David, after taking the inoculations did your health begin to deteriorate?

Mr. SMITH. Within 72 hours I had flown back from the front in a helicopter to pick up some gear. I picked up a vehicle and a van and I was headed back to the front, which is an 8-hour drive from my closest camp. I got sick on the way up there. The A driver had to take over.

Mrs. CHENOWETH. And that's when you lost consciousness and woke up——

Mr. SMITH. It went on into that. It went into a seven day period.

Mrs. CHENOWETH. Thank you. Thank you, gentlemen.

The CHAIRMAN. Mr. Reyes.

Mr. REYES. Thank you, Mr. Chairman. I would like to echo the comments that we appreciate your service to your country.

Mr. Smith, I just have one question. You stated that a VA doctor had told you you were terminal?

Mr. SMITH. Yes, sir. From the West Los Angeles CCEP program. He was a consult for neurology, Dr. Baumzweiger, William Baumzweiger.

Mr. REYES. And your compensation is 60 percent?

Mr. SMITH. As of now, yes, sir. As of Friday I received a call from America Legion here in Washington, DC, who had received a call from Jack Garrison of Central Office notifying me that my compensation had been granted and I would have a check in 20 days.

Mr. REYES. For 60 percent disability?

Mr. SMITH. Yes, sir. Back to the day of discharge, July 12, 1991.

Mr. REYES. Thank you. That's all.

The CHAIRMAN. Thank you, sir. Mr. Bilirakis.

Mr. BILIRAKIS. Mr. Chairman, just very quickly.

Mr. Davis mentioned the pre-deployment medical screening and how thorough it was. You indicated that all the men going to the Gulf were in excellent health. Did you gentlemen experience that pre-deployment screening also, medical screening? Mr. Smith?

Mr. SMITH. No, sir. No pre-deployment screening.

Mr. BILIRAKIS. You did not? Mr. Wickline?

Mr. WICKLINE. Again, things were rather rushed so there wasn't a lot of screening done.

Mr. BILIRAKIS. There wasn't a lot of screening done is what you said?

Mr. WICKLINE. No. No.

Mr. BILIRAKIS. So we really don't have a history before and after, if you will. If we do in Mr. Davis' case, and possibly your unit, but not in every case. Is that right?

Mr. DAVIS. The reason why I guess I spoke to that was because we were a national guard unit. I guess if you were familiar with deployment, a lot of times National Guard Reserve units, they have to go to a mobilization process which takes a period of time.

During that time, the months time, we had physicals, training, checkup this, checkup that, alarms calibrated and recalibrated, and calibrated again. They did go off several times over there. These things were supposed to be checked by the experts prior to going to deployment.

As far as the question about the anthrax shot, it didn't appear in anybody's records in my unit, out of 160 something personnel. Every shot you get in the military appears in the shot record. It's annotated, it's supposed to be anyway. It doesn't appear in 160 some odd troops, that's immediate troops, prior to me becoming a base commander.

Mr. BILIRAKIS. Mr. Smith, you said that in the 9 years that you were in, you didn't have any—you had physicals, obviously, didn't you?

Mr. SMITH. Yes, sir. I was a first class. I maintained a first class PFT for the entire 9 years. I was also an elite athlete for the Marine Corps. As I stated, I earned four certificates of achievement from the Department of Defense.

Mr. BILIRAKIS. So as far as any medical history is concerned, there is something in the record. When would maybe the latest one have been closest to the deployment would you say?

Mr. SMITH. My re-enlistment physical, 1987.

Mr. BILIRAKIS. 1987, 4 years I guess before the deployment.

Mr. Wickline, do you have any history in that regard? You have to have if you were——

Mr. WICKLINE. Of course there was some medical history. As far as a deployment physical, I don't really recall a specific deployment physical being done. We were pretty much lined up for shots and sent on our way.

Mr. BILIRAKIS. But I believe there's some testimony earlier by one of the groups, I guess the VA or the DOD, to the effect that there are serum samples that are kept. So there would have been serum samples for each one of you.

The CHAIRMAN. I don't think they did it then, Mike, but they are doing it now.

Mr. BILIRAKIS. Oh. They are doing it now, but they did not do it then.

Mr. SMITH. Right. They are just doing it now. They didn't do it back then.

Mr. BILIRAKIS. Thank you, gentlemen. Thanks again for serving all of us.

The CHAIRMAN. Any other questions? Let me ask a very quick question of you, Mr. Wickline. You mentioned a doctor that was not interested in your records. Was that a VA doctor at a VA hospital?

Mr. WICKLINE. Yes. It was.

The CHAIRMAN. In Oklahoma?

Mr. WICKLINE. In Oklahoma, yes.

The CHAIRMAN. Thank you.

Mr. WICKLINE. Can I mention, sir? This isn't an isolated incident. This has happened nearly every time I have walked into a VA hospital. If I walk into a VA hospital, go to the out-patient clinic or make an appointment with a doctor, specifically ask to be treated for Gulf War illness, I am denied plain and simple. I specifically asked the doctor, are there not facilities set up for the treatment and diagnosis of Gulf War illnesses, he said yes, but they are not available to you. I have gotten this answer numerous times. This is not an isolated incident.

Mr. BILIRAKIS. Mr. Chairman, I wrote it down. Forgive me, I hope I didn't interrupt before you finished. I wrote a statement down by one of the gentleman who testified earlier. The veterans should contact the VA Administration and tell them that they want to be treated for Gulf War Syndrome.

Mr. WICKLINE. I contacted the patient representatives at the VA hospital who were supposed to be our liaison with the VA health care organizations. I was told by them that they could not do anything more than schedule appointments. So I scheduled an appointment. Every time I call them, I schedule an appointment.

The CHAIRMAN. Gentlemen, thank you very much. We appreciate your service to this country. We appreciate your patience for waiting today. This committee will do everything we can to expedite this procedure. Thank you very much. Thanks to the Members for having the patience to sit here through this long meeting. Thank you very much. If there's no objection, the meeting is adjourned.

[Whereupon, at 5:44 p.m., the subcommittee adjourned, subject to the call of the Chair.]

A P P E N D I X

**OPENING STATEMENT
HONORABLE BOB STUMP
COMMITTEE ON VETERANS' AFFAIRS
ON
PERSIAN GULF WAR VETERANS' ILLNESSES
FEBRUARY 11, 1997**

**TODAY'S HEARING ON THE HEALTH CONCERNS
OF PERSIAN GULF VETERANS IS OUR
ELEVENTH SUCH HEARING, AND FAR FROM
OUR LAST ON THIS SUBJECT.**

**BUT MUCH HAS BEEN LEARNED SINCE OUR
LAST HEARING.**

**WE WON'T GET ALL THE ANSWERS OR
RESOLVE ALL THE ISSUES TODAY.**

**BUT WE WILL FOLLOW THIS ISSUE WHEREVER
IT TAKES US.**

**IF ADDITIONAL LEGISLATION IS NEEDED, WE
WILL TAKE IT UP AND MOVE IT SWIFTLY.**

**THIS AFTERNOON WE WILL HEAR TESTIMONY
FROM SCIENTISTS, GOVERNMENT OFFICIALS,
AND SPOKESMEN FOR OUR VETERANS
ORGANIZATIONS.**

TESTIMONY TODAY FROM INDIVIDUAL VETERANS WILL ALSO REMIND US OF THE IMPORTANCE OF PROVIDING EMPATHETIC CARE, TIMELY BENEFITS, AND, ULTIMATELY, REAL ANSWERS.

FINDING ANSWERS HAS BEEN SLOW AND ELUSIVE.

THERE IS SOME ENCOURAGEMENT, THOUGH, IN THE FACT THAT A GREAT DEAL OF RESEARCH ON GULF WAR ILLNESSES HAS ALREADY BEEN DONE, AND MUCH MORE IS UNDERWAY.

HOPEFULLY, THESE HEARINGS WILL HELP US UNDERSTAND THE LIMITATIONS, AS WELL AS IMPORTANCE TO THESE ISSUES, OF SCIENTIFIC INQUIRY.

CONCERNS REGARDING PERSIAN GULF VETERANS' ILLNESSES HAVE SPARKED MANY THEORIES REGARDING BOTH CAUSE AND CURE.

WE WILL NOT HELP OUR VETERANS, HOWEVER, BY SUBSTITUTING OUR OWN JUDGMENT FOR

**THAT OF THE EXPERTS IN DETERMINING THE
MOST FRUITFUL AVENUES FOR FURTHER
RESEARCH INQUIRY.**

**AND WE MUST NOT LET FRUSTRATION
REGARDING THE SEARCH FOR ANSWERS
OVERTAKE OUR RESPONSIBILITY FOR
JUDICIOUS DECISIONMAKING.**

**IN THAT REGARD, THE PRESIDENTIAL
ADVISORY COMMITTEE ON GULF WAR
VETERANS' ILLNESSES HAS ACCOMPLISHED
IMPORTANT WORK, AS HAS THE INSTITUTE OF
MEDICINE.**

**I HOPE THE WORK OF THESE EXPERT PANELS
WILL HELP US AGREE ON WHERE WE GO FROM
HERE.**

STATEMENT OF HONORABLE LANE EVANS
RANKING DEMOCRATIC MEMBER
PERSIAN GULF WAR ILLNESSES
OPENING STATEMENT
FEBRUARY 11, 1997

THANK YOU MR. CHAIRMAN.

I WELCOME EACH WITNESS SCHEDULED TO TESTIFY TODAY. THANK YOU FOR THE EFFORT YOU HAVE MADE TO PARTICIPATE. I ENCOURAGE EACH WITNESS TO BE COMPLETELY CANDID AND TO ASSIST THIS COMMITTEE TO THE BEST OF YOUR KNOWLEDGE AND ABILITY. WE ARE INDEBTED TO THOSE WHO SERVED IN THE GULF. WE ARE MORALLY OBLIGATED TO CARE FOR OUR VETERANS WHO BORE THIS BATTLE AND FOR THEIR SPOUSES AND CHILDREN.

YOUR CANDID TESTIMONY AND RESPONSE TO QUESTIONS CAN HELP US BETTER MEET OUR SOLEMN OBLIGATIONS TO THESE VETERANS.

ACCORDING TO THE CHAIRMAN'S LETTER OF INVITATION, THE FOCUS OF TODAY'S HEARING IS THE FINAL REPORT OF THE PRESIDENT'S ADVISORY COMMITTEE ON PERSIAN GULF WAR VETERANS' ILLNESSES. THIS REPORT ADDRESSES A WIDE RANGE OF ISSUES AND I EXPECT THIS HEARING TO DO THE SAME.

MR. CHAIRMAN, I ANTICIPATE SOME MEMBERS OF THE COMMITTEE MAY HAVE ADDITIONAL QUESTIONS FOR SOME WITNESSES FOLLOWING THE CONCLUSION OF THIS HEARING. I REQUEST ALL MEMBERS BE GIVEN THE OPPORTUNITY TO SUBMIT QUESTIONS IN WRITING TO WITNESSES AND THOSE QUESTIONS, AND THE RESPONSES TO THEM, WILL BE INCLUDED IN TODAY'S HEARING RECORD.

I COMMEND PRESIDENT CLINTON FOR ESTABLISHING THE ADVISORY COMMITTEE AND ITS MEMBERS AND STAFF FOR THE IMPORTANT SERVICE THEY HAVE RENDERED. BY ALL ACCOUNTS THEIR WORK HAS BEEN

THOROUGH, COMPETENT, EFFECTIVE AND CANDID. I HOPE FUTURE GOVERNMENT ADVISORY COMMITTEES WILL CONDUCT THE PEOPLE'S BUSINESS IN THE SAME MANNER AND CARRY OUT THEIR MANDATE AS WELL.

AGAIN, I WANT TO PUBLICLY THANK THE CHAIRMAN FOR SCHEDULING THIS HEARING EARLY IN THE 105TH CONGRESS. THE CHAIRMAN KNOWS I FEEL STRONGLY THAT OUR COMMITTEE MUST MORE ACTIVELY ADDRESS THE CONCERNS AND PROBLEMS OF GULF WAR VETERANS.

THE CHAIRMAN HAS INDICATED TODAY'S HEARING IS THE FIRST OF SEVERAL THAT OUR COMMITTEE WILL HOLD ON PERSIAN GULF ISSUES THIS CONGRESS THE MEMBERS ON OUR SIDE OF THE AISLE ARE COMMITTED TO MEETING THE NEEDS AND ADDRESSING THE CONCERNS OF PERSIAN GULF VETERANS.

THE FINAL REPORT OF THE PRESIDENTIAL ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES RECOMMENDS

CONTINUED SCIENTIFIC INVESTIGATION. I SUPPORT RIGOROUS SCIENTIFIC INQUIRY INTO THE CAUSES OF CHRONIC AND OFTEN DISABLING UNDIAGNOSED HEALTH PROBLEMS WHICH MANY PERSIAN GULF WAR VETERANS SUFFER. I HOPE SCIENCE CAN IDENTIFY THE CAUSES OF THESE DEBILITATING CONDITIONS AND PROVIDE CURES.

WE OWE MUCH TO SCIENCE, BUT CONSIDER THIS. EVEN THE MOST KNOWLEDGEABLE AND WELL INFORMED SCIENTISTS CANNOT REACH AGREEMENT ON THE AGE AT WHICH MOST WOMEN SHOULD BEGIN TO REGULARLY RECEIVE MAMMOGRAPHY EXAMINATIONS.

SCIENCE IS A TOOL. IT IS A SERVANT. IT IS NOT THE MASTER. WE MUST NOT FORGET THAT FUNDAMENTAL DISTINCTION. SCIENCE, AT ITS BEST, CAN AID US IN MAKING WISE DECISIONS.

WHILE SCIENCE CAN HELP US, IT CANNOT REPLACE US. WE, NOT SCIENCE, ARE THE

DECISION-MAKERS. WE MUST MAKE THOSE DECISIONS AND THEN TAKE RESPONSIBILITY FOR OUR ACTIONS OR OUR UNWILLINGNESS TO ACT. WE CANNOT ABDICATE OUR RESPONSIBILITY TO SCIENCE. I CERTAINLY WON'T. WE MUST ACCEPT OUR RESPONSIBILITY AND MAKE DECISIONS, EVEN THE TOUGH ONES.

WE CANNOT WAIT, AND EVEN MORE IMPORTANTLY, GULF WAR VETERANS CANNOT WAIT FOR SCIENCE AND HISTORY TO UNAMBIGUOUSLY ANSWER EVERY QUESTION. THE FACT IS, MORE THAN 50 YEARS AFTER WORLD WAR 11, THE HISTORY OF THAT GREAT CONFLICT IS STILL BEING DISCOVERED TODAY. PERSIAN GULF WAR VETERANS CANNOT WAIT 50 MORE YEARS FOR HISTORY AND SCIENCE TO BETTER UNDERSTAND THEIR EXPERIENCE.

WHEN WE SEND MEN AND WOMEN INTO HARM'S WAY ON BEHALF OF THIS NATION, WE ARE INDEBTED TO THEM. NOT JUST RHETORICALLY, BUT MEANINGFULLY. AS

MORAL MEN AND WOMEN WE MUST PROVIDE THE MEDICAL CARE AND TREATMENT VETERANS NEED AND THE COMPENSATION TO WHICH THEY ARE ENTITLED. IF THERE IS LESS THAN TOTAL CERTAINTY ABOUT OUR DECISIONS, LET US ERR ON BEHALF OF THE VETERAN. THESE ARE BENEFITS VETERANS HAVE EARNED.

SEVERAL YEARS AGO, THE OVERSIGHT AND INVESTIGATIONS SUBCOMMITTEE, WHICH I THEN CHAIRED, CONDUCTED A SERIES OF HEARINGS ON PERSIAN GULF WAR ISSUES. I WILL CERTAINLY NEVER FORGET SOME OF THE TESTIMONY THE SUBCOMMITTEE RECEIVED. ONE PANEL OF WITNESSES WERE PERSIAN GULF WAR VETERANS. SOME OF THESE GULF VETERANS WERE RESERVISTS OR GUARDSMEN WHO HAD BEEN CALLED TO ACTIVE DUTY. SOME HAD BECOME ILL IN THE GULF, OTHERS AFTER RETURNING HOME. SOME COULD NO LONGER WORK. SOME WERE BARELY MOBILE. BECAUSE THEY WERE VETERANS, THEY WENT TO VA FOR HELP. VA, QUITE LITERALLY, TURNED THEM AWAY.

THOSE REVELATIONS LED TO ENACTMENT OF IMPORTANT CHANGES IN THE LAW TO BENEFIT PERSIAN GULF VETERANS. THAT IS THE PURPOSE OF HEARINGS LIKE THIS ONE TODAY.

SINCE THEN WE HAVE LEARNED MUCH. WE HAVE LEARNED, FOR EXAMPLE, GULF WAR VETERANS CAN INDEED HAVE CHRONIC ILLNESS WHICH DISABLES, EVEN WHEN THAT CHRONIC CONDITION LACKS A READY DIAGNOSIS. WE HAVE ALSO LEARNED THAT A CHRONIC DISABLING CONDITION MAY NOT BECOME MANIFEST IN GULF WAR VETS UNTIL YEARS AFTER THEY HAVE RETURNED HOME.

MR. CHAIRMAN, I AM OPTIMISTIC OUR COMMITTEE WILL DO THE RIGHT THING FOR GULF WAR VETS. IF MY OPTIMISM IS MISPLACED, HOWEVER, I INTEND TO FIGHT FOR WHAT I BELIEVE IS RIGHT FOR THESE VETERANS.

JOSEPH P. KENNEDY II
8th DISTRICT, MASSACHUSETTS
COMMITTEE ON BANKING AND
FINANCIAL SERVICES

SUBCOMMITTEE
HOUSING AND COMMUNITY OPPORTUNITY,
BANKING MINORITY MEMBERS
DOMESTIC AND INTERNATIONAL
MONETARY POLICY
COMMITTEE ON VETERANS' AFFAIRS

SUBCOMMITTEE
HOSPITALS AND HEALTH CARE
COMPENSATION, PENSION, INSURANCE
AND MEMORIAL AFFAIRS



Congress of the United States

House of Representatives

Washington, DC 20515-2108

STATEMENT OF REP. JOSEPH P. KENNEDY II

PERSIAN GULF WAR SYNDROME

FEBRUARY 11, 1997

2242 RAYBURN BUILDING
WASHINGTON, DC 20515-2108
(202) 225-5111

SUITE 806, THE SCHWAPPY CENTER
529 MAIN STREET
CHARLESTOWN, MA 02129
(617) 242-0200

801(A) TREMONT STREET
ROXBURY, MA 02118
(617) 445-1281

When the men and women who fought in the Persian Gulf War returned home, they thought that the battle had been fought and won. Yet since their return they have discovered a second battle that needs to be fought - a battle to learn the true cause of a mysterious illness that has plagued many of them since the war ended.

Thousands of veterans and military personnel are experiencing debilitating health, with symptoms such as chronic fever, fatigue, memory loss, bleeding gums, dramatic weight loss, and rashes, commonly referred to as "Gulf War Syndrome."

More than four years ago, in September of 1992, the House Committee on Veterans Affairs held its first hearing on the health concerns of Persian Gulf War veterans. At this hearing, the federal government downplayed the severity and scope of the problem -- writing the sick veterans off as mental cases.

I was outraged, and called for a field hearing to be held in Boston that same month. I wanted to give the veterans a chance to testify for the first time about their illnesses and difficulties in receiving care.

Since that time, Congress and the President have launched a series of initiatives for Persian Gulf War veterans. The Veterans' Committee has passed into law provisions granting these veterans priority health care and compensation. Our veterans deserve the best possible care, yet a significant percentage of them have been denied service-connected benefits. I commend Secretary Brown for reviewing the current two year presumptive period, and encourage him to recommend a presumptive period that is open-ended.

Also, in May 1995 President Clinton established the Presidential Advisory Committee on Gulf War Veterans' Illnesses. I would like to commend the Presidential Advisory Committee for their dedication and commitment to investigating Gulf War veterans' illnesses. This Committee has played a crucial role in coordinating and analyzing the activities of government agencies involved in the research effort, and has made a number of important recommendations that will continue to improve the care and service of our veterans.

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Furthermore, the Committee has played a crucial role in refocusing the Department of Defense's investigation into possible troop exposure to chemical and biological weapons. It has called for a critical in-depth investigation of short- and long-term health effects of exposure to Gulf War risk factors, and made important recommendations for additional research.

But despite all of the efforts that have been made to find a cause for the health problems of Persian Gulf War veterans, the underlying causes of the disease still eludes us. And in the search for answers, a number of disturbing facts have been uncovered.

After denying for years that our troops were exposed to chemical weapons, the Department of Defense revealed last June that our troops were in fact exposed. Even more disturbing is the fact that the CIA and the State Department were informed as far back as November 1991 that U.S. troops had explored munitions sites storing chemical weapons.

Now the number of troops reportedly exposed is rising steadily. Initially the number was estimated to be 500. Since June 1996 that number has risen - 500 - 5,000 - 15,000 - 20,000. In fact, we now know that as many as 100,000 troops may have been exposed. We know that the DoD has been receiving information as far back as 1991, yet they waited until 1996 to reveal publicly that American troops may have been exposed to deadly chemical weapons.

This raises a number of important questions. Why did it take the Defense Department 5 years to release this information? What other crucial information has been "misplaced" or "disregarded"? What critical research studies on low-level chemical exposure were denied funding because the DoD denied there was any chemical exposure at all?

In its final report, the Presidential Advisory Committee states that the government acted in good faith, **"with the exception of Department of Defense's investigations in matters related to incidents involving chemical weapons and possible exposures to U.S. troops."** In fact, the Committee went so far as to conclude that DoD efforts were superficial and lacked credibility, and that further investigation on this issue should be conducted by a group other than DoD.

The Veterans Committee must investigate these questions in a timely fashion. Further investigation into the issue of Gulf War Illnesses must be open and transparent. And it must move forward rapidly. Our proud veterans have suffered long enough.

**THE HONORABLE MICHAEL BILIRAKIS
THE HOUSE COMMITTEE ON VETERANS' AFFAIRS
HEARING ON PERSIAN GULF ILLNESSES
FEBRUARY 11, 1997**

THANK YOU, MR. CHAIRMAN.

**FIRST, LET ME TAKE THIS OPPORTUNITY TO COMMEND YOU FOR
HOLDING THIS IMPORTANT HEARING THIS AFTERNOON. I WOULD
ALSO LIKE TO WELCOME OUR WITNESSES TO OUR COMMITTEE.**

**ALMOST ONE MILLION U.S. SOLDIERS SERVED IN THE PERSIAN
GULF REGION FROM AUGUST 1990 THROUGH 1995.
APPROXIMATELY 700,000 OF THEM SERVED DURING OPERATION
DESERT SHIELD/DESERT STORM.**

**MANY OF THESE VETERANS ARE NOW EXPERIENCING
UNEXPLAINED ILLNESSES. THE MOST COMMONLY REPORTED
SYMPTOMS INCLUDE CHRONIC FATIGUE, SKIN RASHES, MUSCLE
AND JOINT PAIN, HEADACHES, MEMORY LOSS, SHORTNESS OF
BREATH, SLEEP PROBLEMS AND GASTROINTESTINAL PROBLEMS.
MANY ACTIVE DUTY SERVICEMEMBERS ARE ALSO EXPERIENCING
THESE SAME SYMPTOMS.**

**THERE HAVE ALSO BEEN REPORTS OF SIMILAR, UNEXPLAINED
ILLNESSES AMONG SOME SPOUSES OF PERSIAN GULF WAR
VETERANS. IN ADDITION, CONCERNS HAVE BEEN RAISED
REGARDING HEALTH PROBLEMS AND BIRTH DEFECTS AMONG THE
CHILDREN OF PERSIAN GULF VETERANS.**

DESPITE A BROAD RANGE OF RESEARCH PROJECTS INTO PERSIAN GULF WAR ILLNESSES, RESEARCHERS HAVE BEEN UNABLE TO IDENTIFY A SINGLE ILLNESS, SYNDROME OR CAUSE OF THE HEALTH PROBLEMS EXPERIENCED BY MANY PERSIAN GULF VETERANS. THIS IS A CONTINUING SOURCE OF FRUSTRATION FOR OUR VETERANS AND THEIR FAMILIES.

SINCE THE END OF THE WAR, OUR COMMITTEE HAS INITIATED A NUMBER OF LAWS TO ASSIST OUR PERSIAN GULF WAR VETERANS. UNDER THESE LAWS,

- ** VA PROVIDES HEALTH EXAMS AND COUNSELING TO PERSIAN GULF WAR VETERANS;

- ** VA PROVIDES PRIORITY HEALTH CARE SERVICES FOR ANY HEALTH PROBLEMS WHICH MAY HAVE BEEN DUE TO EXPOSURE TO TOXIC SUBSTANCES OR ENVIRONMENTAL HAZARDS IN THE GULF;

- ** VA PROVIDES COMPENSATION IN ACCORDANCE WITH CRITERIA ESTABLISHED BY THE SECRETARY FOR VETERANS WHO HAVE DEVELOPED DISABLING MEDICAL PROBLEMS FOLLOWING THEIR SERVICE IN THE GULF.

MANY VETERANS HAVE VOICED CONCERNS THAT THE GOVERNMENT IS NOT DOING EVERYTHING IT CAN TO FIND A SOLUTION TO THEIR ILLNESSES. THIS IS FURTHER COMPLICATED BY RECENT REVELATIONS THAT U.S. SERVICEMEMBERS MAY HAVE BEEN EXPOSED TO CHEMICAL AND BIOLOGICAL AGENTS WHILE IN THE GULF REGION.

OBVIOUSLY, IT IS INCUMBENT UPON US TO DO ALL THAT WE CAN DO TO FIND A SOLUTION TO THE HEALTH PROBLEMS NOW BEING EXPERIENCED BY SOME PERSIAN GULF VETERANS, ACTIVE DUTY PERSONNEL AND THEIR FAMILIES.

THEREFORE, I LOOK FORWARD TO HEARING THE TESTIMONY OF OUR WITNESSES. I AM ANXIOUS TO LEARN OF ANY RECOMMENDATIONS THEY MAY HAVE ON WAYS OUR CURRENT EFFORTS CAN BE IMPROVED.

AS ALWAYS, I LOOK FORWARD TO WORKING WITH YOU AND THE OTHER MEMBERS OF THE COMMITTEE ON ANY SUGGESTIONS THE WITNESSES MAY HAVE ON THE ISSUES BEFORE US TODAY.

THANK YOU, MR. CHAIRMAN.

**The Honorable Bob Filner
Committee on Veterans' Affairs – Persian Gulf War Illness
February 11, 1997**

Mr. Chairman, I want to thank you for agreeing to Mr. Evans' request that the Veterans Affairs Committee hold a hearing on the tragic and difficult issue of Persian Gulf War illness. Because the Presidential Advisory Committee on Gulf War Veterans' Illness has submitted its findings, and other widely-publicized studies have recently been completed, this hearing is timely and appropriate.

I also commend the Ranking Democrat on the Committee, Lane Evans, for introducing H.R. 466, the Persian Gulf War Veterans Compensation Act of 1997. This measure would extend the presumptive period during which a Persian Gulf War veteran with chronic, undiagnosed illness could establish eligibility for VA compensation from 2 to 10 years following service in the Gulf. This is a sensible and humane measure.

Additionally, the Secretary of Veterans Affairs should be applauded for the careful, thorough, and deliberative manner in which he is making his determination regarding the Gulf War presumptive period. In addition to thoroughly reviewing the available science, Secretary Brown is consulting with veterans and their representatives around the country on this sensitive matter. I look forward to hearing and discussing his conclusions in early March.

The time for accusatory finger pointing and defensive reluctance to share all pertinent, available information is

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long past. Far too much time has passed, as it is. Our responsibility now is to ensure that our American military personnel who served in the Persian Gulf are provided the quality health care they need -- and to ensure that compensation is paid to those individuals whose health problems are associated with their Gulf War service. Research and the scientific investigation into the cause or causes of the Persian Gulf War illness must, of course, continue. But we cannot, and should not, wait for the very complex science associated with Gulf War illness to reach a single, final, undisputed conclusion. That may never come, and our Gulf veterans must not be made to wait any longer. It is time to accept our national responsibility for those men and women we sent to war on our behalf.

Again, Mr. Chairman, thank you for scheduling this hearing so quickly.

Statement of Rep. Luis V. Gutierrez
Committee on Veterans' Affairs
February 11, 1997

Thank you Chairman Stump and Ranking Member Evans for convening these timely hearings.

I am pleased to see Persian Gulf War issues come back to their true home on the Veterans Affairs Committee and I am committed to working with all my Committee colleagues to maintain Persian Gulf concerns as a priority for us this year.

The President's Advisory Committee on Gulf War Illnesses has laid the groundwork in their final report for future initiatives to discover the causes, consequences and remedies for Persian Gulf War Syndrome (PGWS).

Now, we must follow this report with action. Action here on this committee, action in both houses of Congress and by the relevant federal agencies, the Department of Defense, the VA and HHS, to make good on our commitment to the men and women who triumphed in the Gulf on behalf of all Americans.

I remain concerned that we are acting far too slowly to address PGWS.

I feel strongly, as do many of my colleagues on both sides of the aisle, that we must not permit this issue to drag on for twenty years like Agent Orange did.

The Agent Orange Act was enacted into law in 1991, but U.S. participation in the war ended in '73. We took too long to act.

Nevertheless, we can use the Agent Orange example as a guide for our work to provide the adequate care and compensation to the veterans of Operation Desert Storm.

We must seek a similar, comprehensive approach to PGWS, one that gives the benefit of the doubt to the veterans first. Again the clock is ticking and we are losing time.

Statistical evidence suggesting a link between the environmental risk factors and the illnesses suffered by our Gulf War veterans has not been thoroughly examined.

However, statistical evidence of such a link has been surfacing around the country.

Two studies published by the Journal of the American Medical Association (JAMA) demonstrate that Gulf War veterans have a higher rate of illness than other military personnel. The Iowa Persian Gulf Study Group reports that Gulf War veterans have an 11 percent higher prevalence of symptoms of cognitive dysfunction.

Dr. Haley, of the University of Texas, and his colleagues revealed that wartime exposure to combinations of chemicals such as chemical nerve agents, flea collars and anti-nerve gas pills among some Gulf War veterans were associated with chronic neurotoxic syndromes.

While these studies do not necessarily exhibit a causal association between service in the Gulf and physical or mental ailments they do provide a statistical indication of such an affinity.

This is very important because it may take years for scientists to uncover the causal mysteries of PGWS, years in which deserving veterans may not receive the vital health care coverage that they need and deserve.

These statistics--and common sense--tell us that something is wrong. This committee has the responsibility to act to ensure that all deserving Gulf War veterans receive the care and services they need.

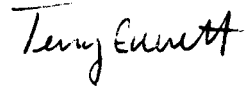
Because of this, I will be considering possible legislation to authorize independent research to examine statistical evidence of Gulf War illnesses. This will enable Congress and the Department of Veterans Affairs to better understand how many Gulf War veterans are sick and thus whether an association exists that merits the provision of health care and compensation for affected veterans.

The need to go beyond the explicit causal evidence is imperative. Giving our sick veterans the benefit of the doubt is a necessity.

I would also like to comment about the efforts of the Pentagon and the VA to investigate low-level chemical agent exposures and their health effects on veterans. While I wish we moved faster in this direction, I am pleased that we are finally taking appropriate steps. I am also impressed by the financial commitment of Defense Secretary Cohen to research along these lines. Let us hope more answers are forthcoming.

I commend the members of the Advisory Committee, the VSOs, federal officials and the veterans who will be testifying before us today. I look forward to developing a partnership with all of you as the Ranking Democrat on the Subcommittee on Health.

Thank you.



**Honorable Terry Everett
Remarks
Committee on Veterans Affairs
on
Persian Gulf War Veterans Illnesses
February 11, 1997**

Mr. Chairman, thank you for having this hearing on this very important issue, and I would like to associate myself with your remarks. I am concerned about the continuing disturbing revelations by Department of Defense.

We all want to insure the quality of compassionate follow-up healthcare and services for our Gulf War veterans. I, too, look forward, with great interest, to hearing the testimony of the Presidential Advisory Committee on Gulf War Veterans' Illnesses, the Institute of Medicine, DoD, Department of Veterans Affairs, the Department of Health and Human Services, our veterans organizations, and our Gulf War veterans.

Also, I would note that 5,898 out of a total of 10,668 to be exact, of pending Persian Gulf War veterans disability claims attributed to environmental hazards were filed in southern region of the United States.

Mr. Chairman, It is important to hold additional hearings on the experiences of our veterans in the Gulf War theater. Hopefully, today's hearing will shed some additional insight on what happened to our veterans and how we can help make them well.

Remarks of the Honorable Sanford D. Bishop, Jr. for the Hearing
to Receive the Report of the Presidential Advisory Commission on
Gulf War Illnesses

Mr. Chairman, I want to thank you and our ranking member, Mr. Evans, for convening this hearing today. I join with other members of this committee in urging that we continue to get to the bottom of Persian Gulf War Illness. We must seek out the truth and find the answers for our Nation's veterans who served us so proudly in the Gulf war.

I am pleased that the Presidential Advisory Committee on Gulf War Veterans' Illnesses will testify before our committee this afternoon. The Advisory Committee was given an enormous task to complete in a short period of time, and I commend those of you who accepted this responsibility. You answered the President's charge by taking an in-depth look at this issue and producing common-sense recommendations aimed at addressing the concerns of not only our Persian Gulf Veterans, but all veterans. I thank you for hard work and dedication to our Nation's veterans and look forward to hearing your remarks.

I believe the report touched on three critical concerns: better risk communication between military personnel, the Department of Defense and the Veterans Administration; the need for sufficient data to study the health concerns of veterans; and the importance of providing much-needed services for veterans with service connected-health problems. Barring national security, I agree it is important to provide troops with full disclosure about the risks associated with their missions. And if available, they should definitely know about potential short and long term effects associated with certain types of theater action. I agree with the Advisory Council recommendation which states assistance should be sought from agencies experienced in risk communication. This type of information will equip these men and women with more knowledge so that they can make more informed decisions with their families. Moreover, this will help lay a more solid foundation of trust between the military and its personnel.

Additionally, the Advisory Committee report concludes that we do not have enough data to adequately address many of the health concerns of Gulf War Veterans. This is unacceptable, and both DOD and VA should coordinate their efforts to expeditiously resolve this matter. More importantly, swift and thorough action is necessary so that we may restore our veterans' faith in our government.

On another front, our continuing goal must be to provide our Persian Gulf Veterans quality services for their health care needs and the needs of their families. It is our job to ensure that the necessary resources, programs, and policies are in place to assist them.

As one of the committees with jurisdiction over these matters, we must be steadfast as we work to achieve the best possible results for the men and women who served us so valiantly. They made a firm commitment to protect our Democratic principles when they answered the charge to serve in the Persian Gulf conflict. It is incumbent upon us, as a Nation, to honor our commitment to them by providing adequate medical care, financial resources, benefits, and sufficient information to deal with problems they face. Additionally, we must enhance our efforts to find those who could have been potentially exposed. Moreover, we must continue to fund research programs which will assist us in our efforts to determine the cause of this illness and remedy some of the effects caused by the illness. Finally, we must restore faith in our veterans so that they know we are there for them just as they were there for our great Nation.

In closing, I want to again thank the Advisory Committee for all its hard work in preparing this report. You have provided our committee with many useful recommendations. I also want to thank Chairman Stump, Congressman Evans, and other members for their continued support of our Nations veterans. I look forward to working with you all to address the issues brought before us today.

STATEMENT OF THE HONORABLE SPENCER BACHUS
February 12, 1996

Mr. Chairman,

I appreciate the opportunity for the Committee to review the findings of the Presidential Advisory Committee on Gulf War Veterans' Illnesses.

The plight of these sick Desert Storm veterans is a complicated issue. Six years after the end of the Gulf War, experts are still unable to pinpoint a single cause of illness. Recent admissions by the Department of Defense regarding American troop exposure to chemical weapons have ignited additional concerns about this situation.

I have been very active in working to ensure that these veterans get the care they so desperately need. I have met with numerous veterans whose lives have been dramatically affected by their illnesses. I have been an active participant in several hearings to better understand the concerns and issues facing these veterans, the Department of Defense, and the Veterans Administration in addressing these concerns.

Many questions, however, remain. Only a small percentage of the thousands of veterans who have applied for service connected disability compensation have been successful. However, while the Presidential Advisory Committee on Gulf War Veterans' Illnesses failed to find a link between service in the Gulf and subsequent illnesses, this report goes a long way toward concisely addressing the government's response to this problem. It makes concrete suggestions for improving that response. And perhaps the greatest need for improvement comes in rebuilding the lines of communication between our government and our ill veterans who have grown to mistrust it.

This matter is far from resolved. Our veterans' quest to understand the cause or causes of their health problems is still of primary concern. We must continue to look for answers. This report is a blueprint for the right direction.

**Statement of the Honorable Mike Doyle [PA-18]
Committee on Veterans' Affairs
Hearing on Gulf War issues**

February 11, 1997

First, I would like to thank the Chairman of the Committee, Mr. Stump and the Ranking Member, Mr. Evans for holding this important hearing. As a Member representing a district with one of the highest concentrations of veterans in the nation, I appreciate your attention to the needs and concerns of those who served in the Persian Gulf War.

By now it has been well documented that many veterans who fought in the Gulf conflict are experiencing health problems they had not experienced prior to their service in the Gulf region. While the Federal Government has stepped up its efforts in recent months regarding this situation, more must be done to explain the source of these veterans' conditions and provide them with appropriate treatment.

The number of veterans suffering from what has been labeled "Gulf War Syndrome" and the mysteriousness of the illness makes this effort especially critical. Additionally, the delay in the onset of some veterans' symptoms are worrying other veterans who are not currently ill that they will one day experience the same health problems. The Persian Gulf Veterans Coordinating Board has estimated that roughly 38,000 veterans have already asked to participate in the Comprehensive Clinical Evaluation Program, which was established to provide medical evaluations to Gulf War veterans who have health concerns regarding their service in the Gulf. We owe it to the men and women who risked their lives and health serving in this conflict to find the answers they need to live healthy, productive lives after their Persian Gulf service.

The final report of the Presidential Advisory Committee on Gulf War Veterans' Illnesses, which we are reviewing today, is a first step toward this goal. I want to thank the members of the President's Advisory Committee who are presenting their findings to this Committee and the other members who helped draft the report for their efforts. Your work, combined with other activities being completed by the Departments of Defense and Veterans' Affairs and others, will allow large strides to be made in understanding the health problems being faced by Gulf War veterans. Additionally, the recommendations made in the report can help improve the safety of personnel involved in future military missions abroad.

The most important point to remember as we discuss this issue, however, is that this is an immediate problem for Persian Gulf War veterans. Those veterans experiencing "Persian Gulf Syndrome" and those who are simply concerned about their health status after their tour of duty in the Gulf deserve a quick resolution to their situations.

STATEMENT BY CONGRESSMAN FRANK MASCARA

PERSIAN GULF WAR ILLNESS HEARING

FEBRUARY 11, 1997

GOOD AFTERNOON MR. CHAIRMAN, I WANT TO
THANK YOU FOR AGREEING TO HOLD THIS HEARING
TODAY WHICH WILL LET THIS COMMITTEE BEGIN TO
EXPLORE THE TRAGEDY THAT HAS COME TO BE
KNOWN AS THE GULF WAR SYNDROME.

I JOIN WITH MEMBERS OF THE COMMITTEE
REPRESENTING BOTH SIDES OF THE AISLE IN URGING
THAT TODAY'S MEETING BE CONSIDERED JUST A
BEGINNING. OVER THE COURSE OF THE 105TH
CONGRESS, I WOULD HOPE YOU WOULD AGREE TO
HOLD A SERIES OF HEARINGS THAT WOULD ALLOW
US TO DELVE INTO ALL ASPECTS OF THIS MOST
DISTURBING SITUATION.

FOR A VARIETY OF REASONS, OTHER
CONGRESSIONAL COMMITTEES HAVE TAKEN THE

LEAD AND BEGUN THEIR OWN GULF WAR INVESTIGATIONS. THROUGH HARD WORK AND PERSISTENCE, THEY UNCOVERED THE FACT THAT ON A NUMBER OF OCCASIONS, THOUSANDS OF GULF WAR MILITARY PERSONNEL WERE INDEED EXPOSED TO CHEMICAL WEAPONS.

WHILE WE SHOULD THANK THESE COMMITTEES AND THEIR MEMBERS FOR THEIR COURAGE AND THEIR EFFORTS, ULTIMATELY IT IS OUR RESPONSIBILITY TO SEE THAT THE COUNTLESS GULF WAR VETERANS WHO ARE SUFFERING AS A RESULT OF THEIR SERVICE, LEARN THE TRUTH ABOUT THEIR EXPOSURE AND RECEIVE THE HEALTH CARE AND COMPENSATION THEY DESERVE.

THIS COMMITTEE RIGHTFULLY HAS JURISDICTION OVER VETERANS' HEALTH AND SERVICE-CONNECTED DISABILITY ISSUES AND, FRANKLY, WE NEED TO STAND UP AND RECLAIM OUR TURF.

FOR THE SAKE OF EACH AND EVERY VETERAN WHO WENT TO THE GULF AND LIVED THROUGH THE SAND, THE BUGS, THE OIL FIRES, AND THE SCUD MISSILE ATTACKS, WE MUST PLEDGE TO GET TO THE BOTTOM OF THIS STORY. IN MY OPINION THERE IS NO BETTER NOR MORE APPROPRIATE PLACE FOR THAT TO HAPPEN THAN RIGHT HERE IN THE HOUSE COMMITTEE ON VETERANS' AFFAIRS.

I SAY THIS AS A MEMBER WHO IS A NOT A NEWCOMER TO THIS ISSUE. ALMOST FROM THE DAY IW AS ELECTED IN 1994, I BEGAN RECEIVING CALLS FROM VETERANS IN MY DISTRICT WHO SERVED IN THE GULF. THEIR SYMPTOMS WERE THE ONES WE HAVE ALL HEARD--CHRONIC RASHES, HEADACHES, SLEEPLESSNESS, STOMACH AND INTESTINAL PROBLEMS, MUSCLE AND JOINT PAINS, RARE CANCERS.

MANY WERE YOUNG--TYPICALLY IN THEIR MID-TWENTIES. THEY WERE SICK, THE VA DOCTORS COULD FIND NO CAUSE FOR THEIR COMPLAINTS, AND

THEY PLEADED FOR HELP.

ONE OF THE MOST TRAGIC CASES I HAVE
CONFRONTED INVOLVED MARY RHOADS, AN ARMY
RESERVE SERGEANT FROM CALIFORNIA,
PENNSYLVANIA, WHO WAS INVOLVED IN THE
TERRIBLE IRAQI SCUD MISSILE ATTACK ON HER
BARRACKS IN RIYADH IN LATE FEBRUARY, 1991.

AFTER RETURNING HOME, SHE WAS HIT WITH
ONE ILLNESS AFTER ANOTHER. SHE HAS UNDERGONE
A HYSTERECTOMY, HAS HAD HER GALL BLADDER
REMOVED, AND SUFFERS FROM A SERIOUS LIVER
AILMENT. TODAY, SHE IS VERY WEAK AND IS
FREQUENTLY HOSPITALIZED.

AFTER MANY HOURS OF WORK BY MYSELF AND
MY STAFF, IN THE FALL OF 1995 SHE WAS FINALLY
AWARDED A 100 PERCENT SERVICE-CONNECTED
DISABILITY. IT WAS A HARD FOUGHT CASE AND ONE
OF THE FIRST IN THE NATION IN WHICH THE VA

RECOGNIZED THE GULF WAR SYNDROME AS A CONTRIBUTING FACTOR.

I SAW MARY AS THE “POSTER CHILD” OF THE GULF WAR SYNDROME AND URGED HER TO TESTIFY BEFORE THE PRESIDENT’S ADVISORY COMMITTEE ON GULF WAR VETERANS’ ILLNESS. DESPITE HER RAVAGED BODY, MARY TRAVELED TO WASHINGTON, D.C., AND SPENT MORE THAN AN HOUR BRAVELY TELLING COMMITTEE MEMBERS HOW HER ILLNESS HAD PROGRESSED.

I TRULY BELIEVE HER COMPELLING TESTIMONY HELPED MAKE THE PRESIDENT AND THIS CONGRESS REALIZE THAT GULF WAR VETERANS MUST BE COMPENSATED FOR THEIR PAIN AND SUFFERING AND THAT MUCH MORE NEEDS TO BE DONE TO FIND ANSWERS TO THEIR TERRIBLE ILLNESSES.

BECAUSE SHE IS SUCH A STRONG PERSON, MARY IS GOING TO ONE OF THE WOMEN FEATURED IN A FORTHCOMING BOOK ON THE GULF WAR. SEVERAL

WEEKS AGO, ONE OF ITS AUTHORS, WILLIAM NORTHROP, VISITED ME IN MY DISTRICT OFFICE. HE HAS INTERVIEWED HUNDREDS OF GULF WAR VETERANS AND SAYS THERE IS NO DOUBT IN HIS MIND THAT SOMETHING SERIOUS HAPPENED DURING THE CONFLICT THAT IS MAKING THESE VETERANS TERRIBLY ILL.

HIS OWN THEORY IS THAT WHATEVER IS AT THE ROOT OF THE GULF WAR SYNDROME, IT WEAKENS THE IMMUNE SYSTEM, MAKING THE VETERANS SUSCEPTIBLE TO A VARIETY OF ILLNESSES.

BECAUSE WORD SPREAD IN HE VETERANS' COMMUNITY THAT I WAS ABLE TO HELP MARY, I HAVE RECEIVED LITERALLY HUNDREDS OF CALLS FROM VETERANS ALL OVER THE COUNTRY SEEKING MY ASSISTANCE. I COUNSELED MANY OF THESE VETERANS, REFERRED THEM TO THEIR OWN MEMBERS, AND WITH THE PERMISSION OF ONE MEMBER WAS ABLE TO HELP A FLORIDA WOMAN,

CANDY LOVETT, ALSO RECEIVE A 100 DISABILITY RATING.

HAVING SEEN AND TALKED TO SO MANY SICK GULF WAR VETERANS , I MUST SAY I WAS TAKEN BACK WHEN I READ THAT THE PRESIDENT'S COMMITTEE FELT THE ONLY CREDIBLE LINK BETWEEN THE GULF WAR CONFLICT AND THE ON-GOING PATTERN OF ILLNESSES WE SEE TODAY IS STRESS.

IN MY PART OF THE WORLD, MANY VETERANS FEEL THAT MEANS THE GOVERNMENT BELIEVES THEIR ILLNESS IS "ALL IN THEIR HEADS." ANYONE WHO HAS SEEN FIRST-HAND THEIR DEVASTATED BODIES KNOWS THAT IS SIMPLY NOT THE CASE. THERE IS SOMETHING MORE AT WORK HERE.

I UNDERSTAND THAT DURING THE STAFF BRIEFING, REPRESENTATIVES OF THE PRESIDENT'S COMMITTEE SPENT SOME TIME EMPHASIZING THAT

THE SCIENTIFIC STUDIES AVAILABLE CLEARLY SHOW STRESS AFFECTS THE BRAIN, THE IMMUNE SYSTEM, THE CARDIOVASCULAR SYSTEM AND HORMONAL RESPONSES.

THEY EMPHASIZED THAT WHILE THE GULF WAR CONFLICT BLESSEDLY PRODUCED FEW CASUALTIES, MILITARY PERSONNEL THERE LIVED UNDER HELLISH CONDITIONS-- CONSTANTLY FEARFUL OF A CHEMICAL OR SCUD MISSILE ATTACK--AND THAT STRESS WAS CLEARLY A NATURAL REACTION.

I THINK MORE NEEDS TO BE DONE TO GET THAT MESSAGE OUT TO THE MORE THAN HALF MILLION MILITARY PERSONNEL WHO SERVED IN THE GULF, LETTING THEM KNOW THEIR GOVERNMENT RECOGNIZES A MEDICAL REASON FOR THEIR ILLNESS AND THAT THEY ARE NOT ALONE WOULD SURELY COMFORT THOUSANDS OF AILING VETERANS.

LIKE THE PRESIDENT'S COMMITTEE, I AM MOST

ANGERED BY THE FAILURE OF THE DEPARTMENT OF DEFENSE TO PROMPTLY REVEAL THAT SOLDIERS WERE INDEED EXPOSED TO CHEMICAL WEAPONS AND THEIR TOXIC RESIDUE.

WE NEED TO GET TO THE BOTTOM OF THIS MATTER AND FIND OUT THE TRUTH. SOMEONE WITHIN THE PENTAGON NEEDS TO BE HELD ACCOUNTABLE. LIKE THE PRESIDENT'S COMMITTEE, I FEEL AN INVESTIGATION BY AN INDEPENDENT THIRD PARTY IS THE ONLY WAY CREDIBILITY CAN BE RESTORED.

AS MANY OF YOU KNOW, I AM AN ARMY VETERAN WHOSE FOUR BROTHERS SERVED IN WORLD WAR II. MY FATHER, AN IMMIGRANT FROM ITALY, CAME TO THIS COUNTRY AND SEVERAL MONTHS LATER FOUND HIMSELF IN FRANCE FIGHTING IN WORLD WAR I. HE DID NOT UNDERSTAND ENGLISH VERY WELL AND WAS BAFFLED WHEN HE WAS AWARDED A SILVER STAR IN

THE LATE 1930'S FOR HIS VALIANT SERVICE AND CALLED "A HERO."

FROM HIS EXPERIENCE, MY FAMILY LEARNED FIRST-HAND THE PROBLEMS ASSOCIATED WITH EXPOSURE TO CHEMICAL WEAPONS. I WAS TOO YOUNG TO REALLY UNDERSTAND, BUT MANY TIMES MY FATHER WOULD GASP FOR BREATH AS A RESULT OF EXPOSURE TO MUSTARD GAS. HE DIED AT AGE 53, WHICH I AM SURE IN SOME WAY WAS RELATED TO CHEMICAL EXPOSURE DURING WORLD WAR I.

OVER THE YEARS, I HAVE SEEN OUR NATION FUMBLE ITS RESPONSE TO THE VETERANS WHO WERE EXPOSED TO ATOMIC RADIATION AND AGENT ORANGE, TO THE POW-MIA SITUATION, AND NOW TO CHEMICAL WEAPONS EXPOSURE IN THE GULF WAR. WE CANNOT LET THIS HAPPEN AGAIN. IT IS UNFAIR.

THESE MILITARY PERSONNEL SERVED OUR COUNTRY IN ITS TIME OF NEED. THEY DID SO

BRAVELY AND COURAGEOUSLY. WE OWE THEM A DEBT OF GRATITUDE AND THEY CERTAINLY DESERVE TO BE TREATED BETTER.

WE DO NOT NEED ANY FURTHER DISASTERS. WE NEED TO GET IN PLACE NOW, NOT LATER, A PROCEDURE THAT WILL LET US SYSTEMATICALLY AND SCIENTIFICALLY REVIEW THE HEALTH STATUS AND FIGHTING EXPERIENCES OF OUR SOLDIERS BEFORE THEY GO INTO BATTLE, DURING CONFLICTS, AND PERIODICALLY IN THE FOLLOWING YEARS.

WITH THAT KIND OF QUALITY DATA BASE, AND AN OPEN AND TRUTHFUL DIALOGUE WITH MILITARY PERSONNEL ABOUT THE RISKS THEY FACE, THE CONFUSION AND ANGER FELT BY SO MANY VETERANS WHO BELIEVE THEIR COUNTRY HAS FORGOTTEN AND ABANDONED THEM WOULD CERTAINLY BEGIN TO SUBSIDE.

WE MUST STOP THIS TRAVESTY AND WE MUST
STOP IT NOW!

THANK YOU AGAIN MR. CHAIRMAN.

--THE END--

CONGRESSMAN DAN SCHAEFER
11 FEBRUARY 1997
HOUSE COMMITTEE ON VETERANS'
AFFAIRS
HEARING ON PERSIAN GULF WAR
ILLNESSES

I WOULD LIKE TO BEGIN BY THANKING
CHAIRMAN STUMP FOR CALLING THIS
HEARING. THE BIPARTISANSHIP OF THE
COMMITTEE'S PAST WORK IS HEARTENING.
I HOPE AND EXPECT IT WILL CONTINUE
THROUGHOUT THE 105TH CONGRESS. THE
ISSUE WE ARE DEALING WITH TODAY IS
NOT A PARTISAN ISSUE. DEMOCRATS AND
REPUBLICANS ALIKE ARE UNITED TO
DETERMINE THE CAUSES OF WHAT IS
KNOWN AS "PERSIAN GULF WAR
SYNDROME." THE FACTS SURROUNDING
THIS SYNDROME DEEPLY TROUBLE MANY.
FOR ME, IT IS WHAT IS NOT KNOWN
ABOUT THIS MYSTERIOUS ILLNESS THAT IS
CONCERNING.

OUR BRAVE VETERANS, WHO WERE
WILLING TO SACRIFICE THEIR LIVES ON
FOREIGN SOIL, DESERVE ONLY ONE THING
FROM THE GOVERNMENT THAT SENT THEM
THERE: THE TRUTH. THIS HEARING,
WHICH I HOPE IS ONLY THE FIRST OF A
SERIES, IS A STEP TO PROVIDING OUR

**PERSIAN GULF WAR VETERANS THIS
SATISFACTION.**

**I WOULD ALSO LIKE TO COMMEND THE
PRESIDENTIAL ADVISORY COMMITTEE ON
GULF WAR VETERANS' ILLNESSES FOR
THEIR HARD WORK AND DETERMINATION
ON BEHALF OF THESE VETERANS. IT IS
IMPORTANT TO REMEMBER, HOWEVER,
THAT THE CONCLUSIONS REACHED BY THE
ADVISORY COMMITTEE ARE ONLY THE
PRELIMINARY FINDINGS IN OUR QUEST FOR
THE TRUTH. ITS REPORT SHOULD BE USED
AS A BASIS FOR FURTHER STUDY. ITS
FINDINGS AND RECOMMENDATIONS
SHOULD BE TAKEN SERIOUSLY. BUT THE
SEARCH FOR FURTHER DETAILS AND
INFORMATION MUST GO ON. ONLY BY SO
DOING, CAN WE GIVE VETERANS OF
FUTURE CONFLICTS COMFORT THAT THEIR
GOVERNMENT WILL PROVIDE PROMPT AND
JUST ANSWERS TO THEIR MEDICAL
CONCERNS, AS IS THEIR DUE.**

**THANK YOU AGAIN, MR. CHAIRMAN. I
EAGERLY ANTICIPATE WORKING TOGETHER
WITH THE MEMBERS OF THE COMMITTEE,
ON BOTH SIDES OF THE AISLE, TO BRING
THE SUFFERERS OF PERSIAN GULF WAR
SYNDROME ANSWERS.**

Donna Ailventre Reef

OPENING REMARKS - VETERANS AFFAIRS COMMITTEE
HEARING ON PERSIAN GULF WAR VETERANS' ILLNESSES

February 11, 1997

Thank you, Mr. Chairman, for scheduling this session which represents an opportunity to review the findings of the Presidential Advisory Committee on Gulf War Veterans' Illnesses.

Today's hearing is a true reflection of the commitment of both the Congress and Administration to address the concerns of Veterans as well as all Americans regarding our men and women who saw action in the Gulf.

As a new member to the Veteran's Committee, it is my understanding that there have been numerous hearings with regard to Gulf War Veterans Illnesses. Within my district the 16th of Texas, which includes Fort Bliss, there are numerous veterans from the Persian Gulf War.

Through this committees oversight, on behalf of those veterans in my district and throughout the country, the proper administration of health care, benefits, and recommendations for future deployments of Americans troops is our goal. I want to commend the President's committee for the comprehensive examination they have conducted to evaluate the government's response on this issue.

I look forward to this afternoon's testimony by the Presidential Advisory Committee members, which will certainly further this committees ongoing investigations and oversight in this matter.

Statement of Representative Helen Chenoweth:

Mr. Chairman, I would like to express my profound appreciation for this opportunity to serve on the Committee on Veterans' Affairs. I have always been a strong supporter of America's veterans, and have tried to seize every opportunity to see that they receive the care and attention they deserve. This committee membership will give me a chance to truly make a difference in the lives of those who have served our country. I look forward to working with you and with other members of the committee, on both sides of the aisle, and to helping maintain the bipartisan spirit that has distinguished this committee.

I am pleased that my first committee activity is this hearing on Gulf War Syndrome, and that my first contribution is the testimony of Persian Gulf War veteran David Smith.

When Americans ask men and women to serve in our nation's armed forces, we make them certain promises. One of the most important is the promise of proper health care, but tragically, for many veterans of Operation Desert Storm, that promise has been broken.

Former-marine Corporal David Smith fought bravely during Operation Desert Storm, but for him, the battle did not end when the conflict was over. For the last six years, he has fought a bureaucratic war to win the treatment he requires and the compensation he deserves. Six years ago David Smith was healthy and strong -- he set a Marine squat record of 765 pounds in the 242-pound division. Since he returned from the Gulf, he has suffered from a swollen liver, internal bleeding, a recurring testicular inflection, depression, irritable bowels, chronic digestive trouble, weight loss, joint aches, memory loss, sensitivity to light and yeast infection in the upper layers of his skin.

The VA clinic in West Los Angeles prescribed morphine for pain, but after two months, the prescription ran out. Smith went to the nearest VA hospital in Walla Walla, Washington, but because the Walla Walla facility rejected the diagnosis of the West Los Angeles facility, he was unable to renew his prescription and had to suffer the agony of morphine withdrawal. All the

while, the disability pension he so desperately needed was denied because the VA rejected the "service connection" of his illness.

Ironically, David Smith received an "advisory opinion" from the VA recommending some of his illnesses be considered service connected the same day he received an invitation to testify before Congress. I believe it is important for us to determine the reason for the VA's sudden change of heart. While this part of the battle may be over for David Smith, for many other Gulf War veterans, the battle is just beginning.

The report of the Presidential Advisory Committee on Gulf War Veterans (PAC) is a step in the right direction, especially the conclusion that many veterans have illnesses likely to be connected to their service in the Gulf. We must now follow up on the PAC's recommendation for additional research into the long-term health effects of low-level exposures to chemical warfare agents and the synergistic effects of pyridostigmine bromide with other Gulf War risk factors. We must also look further into the Department of Defense (DOD) effort to assess possible exposures of U.S. troops to chemical warfare agents in the Gulf. I am especially concerned by the PAC's conclusion that DOD's investigations were superficial and unlikely to provide credible answers to veterans' and the public's questions. Last we must find and root out the cause of the bureaucratic nightmare David Smith and other Operation Desert Storm veterans have experienced after the war.

It is my hope that these hearings will lead to administrative and, if necessary, legislative measures that enable victims of Gulf War Syndrome to receive the care they need and deserve. I think we can all agree, the time has come to take action to keep our promises to Gulf War veterans.

Again, thank you for giving me the opportunity to be here and to present a witness. I look forward to working on a productive, objective, and bipartisan Committee on Veterans' Affairs in the 105th Congress.



Presidential Advisory Committee on Gulf War Veterans' Illnesses

Testimony of

Major Marguerite Knox

Accompanied by

Holly L. Gwin, Deputy Director/Counsel
Mark A. Brown, PhD, Senior Policy Analyst

"Presidential Advisory Committee on Gulf War Veterans' Illnesses: Final Report"

U.S. House of Representatives

Committee on Veterans Affairs

February 11, 1997

President Clinton established the Presidential Advisory Committee on Gulf War Veterans' Illnesses in May 1995 to ensure an independent, open, and comprehensive examination of health concerns related to Gulf War service. The Committee, a 12-member panel made up of veterans, scientists, health care professionals, and policy experts, held 18 public meetings between August 1995 and November 1996. We heard invited testimony and received public comment at each meeting. Staff held in-house consultations, received briefings, conducted literature reviews, interviewed veterans, and reviewed government documents throughout our tenure. We analyzed information on the full range of activities specified in our charter—research, coordinating efforts, medical treatment, outreach, reviews conducted by other governmental and nongovernmental bodies, risk factors (exposure and health effects), and chemical and biological weapons—to reach our findings and recommendations. The *Final Report* presents the Committee's conclusions in three major parts:

- an evaluation of the government's response to Gulf War veterans' illnesses;
- an evaluation of available data on the nature of Gulf War veterans' illnesses; and
- an evaluation of available data on the health effects of Gulf War risk factors.

Findings and recommendations specific to the needs of Gulf War veterans appear throughout the *Final Report* and are summarized here.

The Committee's primary focus was on Gulf War veterans' illnesses, but parallels with the health concerns of Vietnam veterans became increasingly obvious over time. Thus, the Committee also decided to include in its analysis, recommendations on how to anticipate and avoid post-conflict health concerns.

ADDRESSING GULF WAR VETERANS' ILLNESSES

Overall, the Committee is encouraged by the government's response to the range of health-related problems experienced by Gulf War veterans. We found the Vet Centers and Persian Gulf Family Support Program established by the Department of Veterans Affairs (VA) to be effective outreach programs and recommend that these field-based initiatives serve as models for health education and risk communication campaigns.

The Committee agrees with the Institute of Medicine's conclusion that the clinical evaluation programs of the Department of Defense (DOD) and VA are excellent for the diagnosis of Gulf War veterans' illnesses. We found some shortcomings in the availability of treatment, particularly with regard to mental health and reproductive health, and recommend better follow-up care in these areas.

The Committee found that the government's research portfolio is appropriately weighted toward epidemiologic studies and studies on stress-related disorders that are likely to improve our understanding of Gulf War veterans' illnesses. To close gaps in the current knowledge base, we recommend additional research on the long-term health effects of low-level exposures to chemical warfare agents and on the synergistic effects of pyridostigmine bromide—a chemical warfare agent pretreatment—with other Gulf War risk factors. We also recommend more emphasis on basic and applied research on the body's physical response to stress.

The existing knowledge base, including results from epidemiologic studies of Gulf War veterans, data from clinical evaluation and treatment programs for Gulf War veterans, and published literature from decades of toxicologic research, enabled the Committee to reach some conclusions about the nature and causes of Gulf War veterans' illnesses. We found that:

- among the subset of the Gulf War veteran population examined in the ongoing clinical and research programs, many veterans have illnesses likely to be connected to their service in the Gulf.
- current scientific evidence does not support a causal link between the symptoms and illnesses reported today by Gulf War veterans and exposures while in the Gulf region to the following environmental risk factors assessed by the Committee: pesticides, chemical warfare agents, biological warfare agents, vaccines, pyridostigmine bromide, infectious diseases, depleted uranium, oil-well fires and smoke, and petroleum products.
- stress is known to affect the brain, immune system, cardiovascular system, and various hormonal responses. Stress manifests in diverse ways, and is likely to be an important contributing factor to the broad range of physical and psychological illnesses currently being reported by Gulf War veterans.

Currently, the extent of service-connected illness among Gulf War veterans is unknown, but the Committee anticipates results from the large, population-based epidemiologic studies now underway will shed light on this issue. In addition to the government's existing research, the Committee also recommends that mortality studies of Gulf War veterans continue, since some health effects, such as cancer, would not be expected to appear until a decade or more after the end of the Gulf War.

Although somewhat slow to act at the end of the Gulf War, the government is now providing appropriate medical care to Gulf War veterans and has initiated research in the areas most likely to illuminate the causes of their illnesses. The Committee identified ways to fine-tune those efforts, but found that, for the most part, the government has acted in good faith to address veterans' health concerns.

The Committee takes issue with the government's performance in one key area: investigation of possible exposures of U.S. troops to chemical and biological warfare agents in the Gulf. We found substantial evidence of site-specific, low-level exposures to chemical warfare agents. Moreover, we found DOD's investigations to date superficial and unlikely to provide credible answers to veterans' and the public's questions. DOD's failure to seriously investigate chemical warfare agent exposures also adversely affected decisions related to funding research into possible health effects of low-level exposures to chemical warfare agents. At the Committee's final meeting in November 1996, DOD announced plans to revamp its investigatory and research programs related to low-level chemical warfare agent exposure. The Committee believes these efforts—combined with independent, high-quality oversight—could begin to restore public confidence in the government's investigations of possible incidents of chemical warfare agent exposure. Given that these steps come too late for the Committee to evaluate, however, we emphasize the importance of the following recommendation:

- To ensure credibility and thoroughness, further investigation of possible chemical or biological warfare agent exposures during the Gulf War should be conducted by a group independent of DOD. Openness in oversight activities—including public access to information and veteran participation—public notice of meetings, opportunity for public comment, and regular reporting are essential. Full public accountability is critical.

The government has a significant amount of ground to recover with Gulf War veterans and the American public, who have come to question whether a lack of data—on possible chemical warfare agent exposures, on the pre- or post-deployment health of veterans, or on the location of troops in-theater—indicates a lack of commitment to veterans' health. We recognize the many laudatory actions taken to address the concerns of Gulf War veterans, but the Committee believes the government can do a better job of anticipating and avoiding these types of problems. We offer the following findings and recommendations in that spirit.

AVOIDING POST-CONFLICT HEALTH CONCERNS

The Committee was impressed by the professionalism of the individuals responsible for the government services we evaluated. We believe the expertise needed to improve technical performance and implement policy and procedural changes resides within the government, but we also believe that DOD and VA have much to learn from their peers in other agencies. Therefore, the Committee recommends that:

- A Presidential Review Directive (PRD) be issued to instruct the National Science and Technology Council (NSTC) to develop an interagency plan to address health preparedness for and readjustment of veterans and families after future conflicts and peacekeeping missions. The President's Committee of Advisors on Science and Technology and other nongovernmental experts, as appropriate, should be asked to review the plan 12 months after the PRD is issued and again at 18 months to ensure national expertise is brought to bear on these issues.

The NSTC's agenda should include the following recommendations for better communication, data, and services, which were developed during the Committee's evaluation of issues related to Gulf War veterans' illnesses.

Better Communication

Clearly, the volunteers who serve in defense of our Nation deserve complete and accurate information about the risks they face. An open democracy demands that the public, as well, has the opportunity to engage in policy debates that accompany the commitment of troops abroad. Therefore, the Committee recommends that:

- DOD and VA immediately develop and implement a comprehensive risk communication plan. This effort should move forward in close cooperation with agencies that have a high degree of public trust and experience with risk

communication, such as the Agency for Toxic Substances and Disease Registry and the National Institute for Occupational Safety and Health.

- FDA solicit timely public and expert comment on any rule that permits waiver of informed consent for use of investigational products in military exigencies. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long-term followup of individuals who receive investigational products; review by an institutional review board outside of DOD; and additional procedures to enhance understanding, oversight, and accountability.

Better Data

Many of the health concerns of Gulf War veterans may never be resolved fully because of the lack of data. The Committee identified problems related to missing medical records, the absence of baseline health data, inaccurate records of troop locations, and incomplete data on the health effects of what should have been viewed as reasonably anticipated risks. To help prevent similar problems in the future, we recommend that:

- DOD officials at the highest echelons, including the Joint Chiefs of Staff and the Commanders in Chief, assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data in the field (including classified information, if and when it is needed). DOD and VA should adopt standardized recordkeeping to ensure continuity.
- the Persian Gulf Veterans Coordinating Board and other appropriate departments and agencies be charged to develop a protocol to implement the following recommendation, which was made in the Committee's *Interim Report*: Prior to any deployment, DOD should undertake a thorough health evaluation of a large sample of troops to enable better postdeployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services, including timely postdeployment followup.
- the government develop more accurate and reliable methods of recording troop locations to facilitate post-conflict health research. DOD should make full use of global positioning technologies.
- the government plan for further research on possible long-term health effects of low-level exposure to organophosphorus nerve agents such as sarin, soman, or various pesticides, based on studies of groups with well-characterized exposures, including: a) cases of U.S. workers exposed to organophosphorous pesticides; and b) civilians exposed to the chemical warfare agent sarin during the 1994 and 1995 terrorist attacks in Japan. Additional work should include followup and evaluation of an appropriate subset of any U.S. service personnel who are presumed to be exposed during the Gulf War. The government should begin by consulting with appropriate experts, both governmental and nongovernmental, on organophosphorus nerve agent effects. Studies of human populations with well-characterized exposures will be much more revealing than studies based on animal models, which should be given lower priority.

- the government continue to collect and archive serum samples from U.S. service personnel when feasible.
- research on possible causes and methods of prevention of excess mortality from external causes among veterans receives high priority.
- the government consider methods for routinely sampling military populations regarding reproductive health so that an appropriate baseline exists for evaluating reproductive outcomes following deployment. In particular, DOD should consult with the National Center for Health Statistics and strongly consider implementing its National Survey of Family Growth and related methodologies for collecting data.
- the entire federal research portfolio place greater emphasis on basic and applied research on the physical effects of stress and on stress-related disorders.

Better Services

The Nation has long provided care to veterans for service-connected health problems. Unfortunately, the government continues to give short shrift to veterans' legitimate concerns about reproductive health, and society at large continues to stigmatize mental health concerns. Therefore, the Committee recommends that:

- the government conduct a thorough review of VA's policies concerning reproductive health and seek statutory authority to treat veterans and their families for service-connected problems. When indicated, genetic counseling should be provided—either via VA treatment facilities or referral—to assist veterans and their families who have reproductive concerns stemming from military service.
- the government continue and intensify efforts to develop stress reduction programs for all troops, with special emphasis on deployed troops.

Conclusion

Approximately 697,000 men and women answered the call to serve in Operations Desert Shield/Desert Storm. In many important ways—through medical care, outreach, and research—the Nation has begun to pay its debt to these service members. It is essential, now, to move swiftly toward resolving Gulf War veterans' principal remaining concerns: How many U.S. troops were exposed to chemical warfare agents, and to what degree?

A continued and sustained commitment to a healthy future for Gulf War veterans—for all current and future veterans—is a priority for all Americans. This *Final Report* represents the Committee's contribution to that goal. We have given our full dedication to President Clinton's charge and have appreciated the opportunity to serve Gulf War veterans and their families.

U.S. House of Representatives
Committee on Veterans Affairs
11 February 1997

Statement by John C. Bailar III, M.D., Ph.D.
Chair, Department of Health Studies
University of Chicago

I am grateful to the Committee for this opportunity to discuss some aspects of the health of veterans of the Persian Gulf War. I am here as Chair of the Committee at the Institute of Medicine, National Academy of Sciences, titled "Committee to Review the Health Consequences of Service during the Persian Gulf War." We wrote two reports, both available to the public from the National Academy Press. The second report was finished and delivered to the sponsors on 30 September 1996. A short form of my curriculum vitae is attached, and details are available on request. I also wish to state that I do not now, and have not during the past two years, held any Federal grant or contract relevant to the subject matter of this testimony. I regret to tell you that a recent injury prevents my travel. My testimony will be presented by Dr. Philip K. Russell, Professor of International Health, School of Hygiene and Public Health, Johns Hopkins University. Dr. Russell was a very active member of our committee, and can present our views quite well. I understand that he will also be available to answer questions.

The charge to our committee included three elements, lightly paraphrased as:

1. Assess the effectiveness of actions taken by the Secretary of Veterans Affairs and the Secretary of Defense to collect and maintain information that is potentially useful for addressing the health consequences of military service in the Persian Gulf Theater of Operations during the Persian Gulf War.
2. Recommend means to improve the collection and maintenance of such information.
3. Determine whether there is sound scientific basis for an epidemiological study or studies of the health consequences of such service, and if there is sound scientific basis, recommend the nature of the study or studies.

During its three year duration, the committee met sixteen times, and received information from a wide variety of sources, as documented in appendices to our published reports. We heard from veterans, their families, veterans' organizations, military experts, and physicians and scientists from many different scientific and technical disciplines. We made 27 recommendations in our first report, and 18 in the second. Highlights from our recommendations are as follows:

- There is a pressing need for a single, uniform, computerized medical record form and system to cover all military personnel, the National Guard, and reserve units, including hospital admissions, clinic visits, and other medical encounters (such as immunizations), and the record for each person covered should be continuous with his or her medical record in the Department of Veterans Affairs.
- There is also a pressing need for studies to identify and ameliorate risk factors for stress-related symptoms and disorders in military personnel.
- Military preparedness should include provision for the monitoring of exposures of potential medical concern.
- We need research comparing active, reserve, and National Guard troops to determine whether differences in personal characteristics or policies and procedures for mobilization, deployment, and demobilization are associated with adverse health outcomes.
- We need additional and more detailed research on mortality and illness among veterans, specifically including excess accident mortality and the circumstances in which injuries occur, with a view toward prevention.
- There is a need for more detailed and more current information systems to document unit locations.

- There has been inadequate study of the health consequences of having men and women serve together, including stress consequences, and ways to reduce such consequences.
- The epidemiologic capabilities of the armed forces must be strengthened.
- Research sponsored by DoD and/or DVA on health matters should be submitted for publication in the open peer-reviewed literature in a timely manner.
- There should be public announcement of and open competition for funding of research studies related to the health of Persian Gulf Veterans.

The committee also recommends that certain activities already in progress be continued and strengthened. These include longitudinal studies of veterans' health, including mental health; the Defense Medical Epidemiologic Database system; the Naval Health Research Center studies and the DVA National Health Survey; and evaluation of predictors of enrollment in the DVA Persian Gulf Health Registry. In addition, our Committee supported the continuation of research on the possible health effects of leishmaniasis, reproductive outcomes, and the consequences of very low-level chemical exposures, though we make no specific recommendations in these areas.

You will note that the charge to our Committee did not include the study of the so-called "Gulf War Syndrome" (GWS). Thus, we make no recommendations that are directly related to the GWS, though the matter did come up for frequent and intense discussion during our meetings. The Committee was entirely convinced that there are large numbers of sick veterans, some of them seriously disabled by their symptoms, that they need appropriate medical diagnosis and care, and that active investigation into their problems must be continued. We were not, however, able to identify credible evidence that any specific kinds of exposure were responsible for the highly diverse symptoms labeled GWS. Indeed, though we had completed our deliberations by the time of the first disclosures of chemical exposures from the destruction of Iraqi ammunition dumps, our draft report already recognized the possibility of undisclosed or unknown exposures, so that the disclosures—when they came—did not affect our conclusions.

Our Committee reviewed carefully the information provided to us regarding fourteen specific disorders that have been proposed as the basis for GWS, and we could not find even moderately convincing evidence for any of them. These are detailed in Chapter 5 of our second report. Other hypotheses have been proposed since that time, and while the Committee as a whole did not have an opportunity to report on them, my own reading is that there is no more to support these new proposals than to support the fourteen that are discussed in our report.

What is missing, uniformly, is direct evidence that exposure is related to health outcome. We are of course aware of the large number of veterans who have offered testimonials about linkages between exposure and their own health problems, and we are aware of the large numbers of persons who are enrolled in the DVA and DoD registers. These do not and cannot establish cause-effect relationships. The symptoms are extremely common—headache, fatigue, memory loss, bone and joint pains, and so forth—and nearly every person must suffer from most of these during the course of a lifetime. Persons who have specific reasons for directing their attention to possible causes of symptoms (such as service during the Persian Gulf War) may incorrectly relate their symptoms to such exposure, rather than to the normal aches and pains of everyday life that are accepted in civilian settings. Further, the Persian Gulf Veterans were subjected to substantial stress, of a wide variety of types discussed in our report, and stress itself can cause serious, even disabling, symptoms.

Since the time we completed our report, Dr. Hyams and colleagues have published a review and analysis of symptoms in veterans (*Annals of Internal Medicine*). These investigators showed that similar collections of symptoms have been reported by veterans of every US war at least as far back as the Civil War, which is as far back as the records exist. Such symptoms have been reported by veterans in other countries, and they have been reported in civilian populations subjected to great stress, whether from earthquake, famine, military invasion, or other major threats. They have been reported among the Japanese survivors of the atomic bombs. Thus it may not be appropriate to think about a Gulf War Syndrome, but rather about a War Syndrome, or even a Stress Syndrome.

We recognize that very small numbers of veterans had other kinds of health problems that are directly related to their military service, including infection by leishmania, a few other infectious diseases, and injuries related to deployment and battle. Nor is this to deny that any stress-related symptoms are an important result of service in the gulf area; high levels of stress are clearly a consequence of military service, and should be recognized as potentially health-related. Nor does this deny the fact that substantial numbers of troops may have had very low exposures to chemical agents.

Further, it does not deny the importance of continuing present and proposed research to identify other causes, if they should exist. We need to explore every avenue.

In summary, however, we could find no acceptable evidence that the symptoms commonly called "Gulf War Syndrome" have any physical or physiological basis in chemical or any other exposures in the Gulf Theater.

Every hospital and every physician sees patients with symptoms, and sometimes very serious physical disease, for which the exact nature of the diagnosis cannot be determined. These include such things as fevers of unknown origin, extensive and severe dermatitis, life-threatening allergies with no identifiable cause, and many other types of illness. The question, then, is not whether such illnesses appear in veterans of the Persian Gulf War, but whether their frequency is higher than in a suitably matched non-deployed population. Regarding medical problems that lie outside the scope of the usual components of the Gulf War Syndrome, we could find no evidence for such an increase.

We recognize that many people are reluctant to face the fact that severe stress can cause major symptoms and even physical health problems, but we believe that it would be a medical mistake and a serious disservice to our honored veterans to discount this matter and to embrace one or another theory about illness related to a specific exposure. The reason is that the proper diagnosis and treatment of these (or other) symptoms is likely to depend on the cause, and treating a veteran for a chemically-induced condition, when the condition is in fact stress-related, may delay or even prevent more appropriate and more effective therapy for what are undoubtedly real problems.

Again, many veterans have important medical symptoms as a result of their service in the Persian Gulf Theater, some are seriously disabled by these symptoms, and all need appropriate diagnosis and therapy. However, I believe that the most important service that might be offered by this Committee, your colleagues elsewhere in these halls, and others, is to work for a fully objective and thorough reading of the scientific evidence, and to recognize that the stresses of deployment and combat may in themselves cause all or nearly all of the illness that has been reported as the GWS. To state that chemical exposures are the cause of GWS may actually create lifelong dependency and disability.

We are not saying that this matter has yet been proved, and we urge the continuation of appropriate research to investigate each promising new hypothesis. However, erroneous diagnosis and treatment for the wrong disease will be doing these veterans no service.

The report of the Presidential Advisory Committee on Gulf War Veterans Illnesses was issued after our own report had been published, so we had no opportunity to develop a Committee view on it. I have, however, read it myself, and can offer some personal views. It was my privilege to review and offer substantial comment, all on minor matters, regarding the interim report of the Presidential Advisory Committee a year ago, and I was invited to comment on this final report. Unfortunately, I did not have time to do so, but I have read it since then. Overall, that Committee has done a fine job.

Further, where it addresses the same issues as were examined by our IOM Committee, there is almost complete agreement regarding each major point. Differences are matters of tone and emphasis.

In particular, I agree (and I believe that all of our Committee members would agree) with the statement of the Presidential Advisory Committee that, "Current scientific evidence does not support a causal link between the symptoms and illnesses reported today by Gulf War veterans and exposures while in the Gulf region to the following environmental risk factors assessed by the Committee: pesticides, chemical warfare agents, biologic warfare agents, vaccines, pyridostigmine bromide, infectious diseases, depleted uranium, oil well fires and smoke, and petroleum products." Further, I agree with the Presidential Advisory Committee, and I believe our Committee members would agree that, "Stress is known to affect the brain, immune system, cardiovascular system, and various hormonal responses. Stress manifests itself in diverse ways, and is likely to be an important contributing factor to the broad range of physical and psychological illnesses currently being reported by Gulf War Veterans."

I am not aware of any broad-based, independent panel of experts that has looked at this problem and reached a contrary conclusion. Converting one kind of medical problem—the effects of stress—into another kind of problem may create serious lifelong difficulties that could be avoided by grasping the most likely explanation of the GWS now. I believe that there is a clear lesson here for Congress, the Executive Branch, veterans, and the public. There seems to be much reluctance to accept the notion that the Gulf War Syndrome may be a manifestation of stress, combined with heightened awareness of a range of symptoms that we may all have anyway, but such concern about accepting the probable role of stress is misplaced. Stress alone can result in important symptoms as well as psychological problems, and correct diagnosis, with an understanding of causation, is the most reliable route to appropriate treatment and the relief of those symptoms. In the long run, the greatest service you can provide to each of our affected veterans is to convey the message that they are most probably the victims of the extremely stressful conditions that were necessarily a part of their military service in the Gulf.

VETERANS OF FOREIGN WARS OF THE UNITED STATES



THE COMMANDER-IN-CHIEF

STATEMENT OF

JAMES E. NIER

COMMANDER-IN-CHIEF

VETERANS OF FOREIGN WARS OF THE UNITED STATES

BEFORE THE

HOUSE COMMITTEE ON VETERANS AFFAIRS

1:00 P.M.

REGARDING PERSIAN GULF WAR ILLNESSES

WASHINGTON, DC

FEBRUARY 11, 1997

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

On behalf of the 2.1 million men and women of the Veterans of Foreign Wars, I thank you for the opportunity to express the views of the VFW on the very important matter of illnesses that are affecting a number of our Persian Gulf veterans. The VFW has worked diligently in the effort to resolve this controversial issue, and will continue to do so until a resolution is reached that appropriately cares for the veterans involved. I would like to take this opportunity to pledge to you, Mr. Chairman, and to the other distinguished Members who serve with you on the Committee, the VFW's commitment to bringing this issue to a successful close. We look forward to working in unison with you and the Committee in this effort.

Mr. Chairman, several months back the VFW questioned the current two-year presumptive period for undiagnosed illnesses associated with service in the Gulf as being, at the time, unwarranted. After consultation with VA as to the reasons for the two-year presumptive period, the VFW, on October 3, 1996, sent a communiqué to Secretary of VA Jesse Brown calling instead for the establishment of an open-ended presumptive period. The VFW believes that in light of current medical and scientific data, or, more appropriately, lack thereof, in conjunction with the experiences reported by Gulf War

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VFW MEMORIAL BUILDING ● 200 MARYLAND AVENUE, N.E. ● WASHINGTON, D.C. 20002-5799
AREA CODE 202-543-2239 ● FAX 202-543-6719

veterans themselves, it is far too early to establish a time limit as to when exposure symptoms will manifest.

I am pleased to say that Secretary Brown has agreed to our request. We do urge, however, that such a change be implemented at the earliest possible date. If Secretary Brown is unable to do so—he has spoken of a 60 day review period to determine the appropriate length of the presumptive period—then possibly this is something that should be done legislatively. (It is our understanding, however, that Secretary Brown does have the authority to implement such a change per Public Law 103-446.) The VFW will, nonetheless, most assuredly assist the Committee in any way it deems necessary in ensuring that the necessary changes are made at the earliest possible date.

On a related matter, the VFW is extremely concerned about the denial rate for veterans seeking service-connection for "undiagnosed illness" as a result of service in the Gulf. Out of the over 10,000 Gulf War veterans who have been rated for an "undiagnosed illness" claim (Gulf War Illness), only 529 have been service-connected for compensation. (It is likely that the restrictive presumptive period concerning the manifestation of the condition is the primary reason why 95% of all "Undiagnosed-Illness" claims have been denied.)

Given the number of Gulf War veterans who have come forward with claims of illnesses that have yet to be diagnosed, it seems implausible to us that 95% of them have no basis for an "undiagnosed illness" service-connected rating. And while it is our understanding that a number of these veterans are in fact service-connected for other diagnosable ailments attributable to their service in the Gulf, we have great concern for those who are left out in the cold. And as for those who are service-connected for other diagnosable illnesses, there is the risk that they may be not receiving the appropriate treatment for any undiagnosable ailment not deemed service-connected.

The VFW has brought up this matter with VA and the Presidential Advisory Committee on Gulf War Veterans' Illnesses (PACGWVI). In an effort to ensure that no Persian Gulf veteran suffering from any degree of an undiagnosable illness goes uncompensated, we have promoted the need for some type of case definition for "Gulf War Syndrome." Unfortunately, this proposal has been met mostly with resistance. And while we are aware of the intricate problems associated with such an undertaking, we feel the alternative—a situation where individual Persian Gulf veterans might go uncompensated for an undiagnosed illness associated with their service in the Gulf—is far more unacceptable.

Indirectly related to these undiagnosable illnesses is the VFW's concern that the Department of Defense do everything possible to ensure that our troops are adequately protected during any future combat situation where the threat of chemical warfare agent use by an adversary exists. This means providing our troops with the best chemical detection and anti-exposure equipment available. Perhaps if our troops had access to such equipment, then we would not be in the unfortunate situation we find ourselves in today.

We should never again have to question the accuracy and effectiveness of our equipment or vaccinations, such as pyridostigmine bromide, when the lives of our brave servicemen and women are at stake.

Mr. Chairman, the VFW has also for some time pushed for the extension of the President's Advisory Committee on Gulf War Veterans' Illnesses beyond its original date of termination, scheduled for the end of 1996. We are very pleased that the President has recognized the excellent work done by the Advisory Committee and has granted our request, extending the life of the Advisory Committee for another nine months. Furthermore, we also pushed hard for the President to extend to the Advisory Committee additional oversight powers, another request which he granted. Given that certain governmental entities have been less than forthcoming with relevant data and slothful in enacting the appropriate measures, we felt this was a necessary act.

Lastly, I would briefly like to comment on the notion of stress as playing a role in the undiagnosed illnesses associated with service in the Gulf. While it may be true that stress does play a part in these ailments, we find it unfathomable as well as counterproductive to insist that stress is the predominant cause. To say that these ailments are nothing more than in the veterans' heads is an insult. We hope that as the medical and scientific community hones in on the causes and remedies of these illnesses, they are not restricted by the notion that stress is the cause. It would only result in an extreme and potentially dangerous disservice to our ill veterans.

Mr. Chairman, the VFW is pleased that the appropriate amount of attention is being paid to resolving this issue. We feel that with the support of individuals such as yourself and the rest of the House Veterans Affairs Committee, we can find a solution that adequately cares for those veterans whose current ill situation resulted from their unselfish acts for the good of our nation.

Again, on behalf of the Veterans of Foreign Wars of the United States, I thank you for the opportunity to be heard on this most important issue. Thank you.

**Statement of
Thomas Garthwaite, M.D.
Deputy Under Secretary for Health**

**Before the
House Veterans' Affairs Committee
Hearing on Health Issues
of Persian Gulf War Veterans**

February 11, 1997

Mr. Chairman and Members of the Committee, I am pleased to have this opportunity to discuss VA's Persian Gulf War-related programs.

Since the focus of this hearing is on the report and recommendations of the Presidential Advisory Committee on Gulf War Veterans' Illnesses (PAC) I will describe the overall VA response to Persian Gulf veterans' needs with a specific emphasis on those areas within the Advisory Committee's charter.

In the way of background let me discuss a few points about VA's general response. On August 2, 1990, Saddam Hussein invaded Kuwait and the United States responded, sending American military men and women to the Persian Gulf. Ultimately, nearly 700,000 U.S. troops were deployed to the Gulf in Operations Desert Shield and Desert Storm. After months of tense military build-up in a stark desert environment in which our troops were outnumbered, and under constant threat of chemical and biological warfare attacks, a short air war and a four day ground war were successfully fought.

However, for some Persian Gulf War veterans the pain of war was not over, and VA's work was just beginning. Shortly after returning from the Persian Gulf War, some veterans began to report a variety of symptoms and illnesses. In preparation for the needs of our latest combat veterans, VA immediately began development of its Persian Gulf programs. The first component of the VA's comprehensive Gulf War response was the establishment of a health-care program, the VA Persian Gulf Registry health examination program. The Registry was developed in 1991 and implemented in 1992. Persian Gulf

health programs in the early days after the war were already being given high priority and attention. In 1993, at the request of VA, Congress enacted Public Law 103-210, giving Persian Gulf veterans special eligibility for VA health care.

VA's Persian Gulf programs are encompassed in a comprehensive four-pronged approach, addressing relevant medical care, research, compensation, and outreach and educational issues. VA provides Persian Gulf Registry health examinations and follow-up care at its medical facilities nationwide, specialized evaluations at four regional Referral Centers, and readjustment and sexual trauma counseling to Persian Gulf War veterans. To date, more than 63,000 Persian Gulf War veterans have completed Registry examinations, more than 1.8 million ambulatory care visits have been provided to 191,000 unique veterans, more than 19,000 veterans have been hospitalized at VA medical facilities, over 350 veterans have received specialized Referral Center evaluations, and more than 74,000 have been counseled at VA's Vet Centers.

Persian Gulf Registry Examinations

Persian Gulf veterans participating in the Registry examination program have commonly reported that they suffer from a diverse array of symptoms including fatigue, skin rash, headache, muscle and joint pain, memory problems, shortness of breath, sleep disturbances, gastrointestinal symptoms, and chest pain. These symptoms have been treated seriously and they have received appropriate medical evaluations. To date, the diagnoses received by Registry participants do not cluster in one organ system or disease category, but rather span a wide range of illnesses and diagnostic categories. As such, they do not meet the clinical definition of a medical syndrome per se. Having said this, though, in no way diminishes how we view these complaints or what type of evaluation the symptomatic person receives. Also of particular note, 12 percent of the VA Registry examination participants have had no current health complaints but have wished to participate in the examination because they were concerned that their future health might be affected as a consequence of their service in the Persian Gulf War. While 26 percent of

the Registry participants rated their health as poor, 73 percent receiving this examination reported their health as all right to good.

With regard to the possible troop exposure to chemical warfare nerve agents, the Department of Defense has provided VA with a list of 21,799 individuals whom they identified as possibly being present within 50 kilometers of the Khamisiyah Ammunition Storage Area during the demolition period in March 1991. A computer match of the Persian Gulf Health Examination Registry database with this list identified 1,978 veterans, or approximately 9 percent, had completed Registry examinations prior to September 1996. A comparison of the examination results of these individuals with other Registry participants shows that similar types and rates of symptoms, diagnoses, and self-reported health status are reported, but virtually all veterans in the Khamisiyah group reported symptoms at the time of their Registry examinations. Furthermore, those 81 Registry participants who are identified to us by DOD as part being part of the on-site Khamisiyah demolition team report symptoms and are diagnosed with musculoskeletal conditions at a higher rate than the 50 kilometer or general Registry group. This health surveillance data is preliminary and is compiled from evaluations of a non-random, self-selected group of the individuals possibly exposed to nerve agents at Khamisiyah. While this information gives an limited snapshot of the health of some veterans thought to be present at this site in March 1991, the results should not be generalized to the entire Khamisiyah group or be considered definitive. I want to be clear that contrary to certain reports in the media, VA has no evidence of a causal link between the illnesses of Registry veterans and exposure to chemical warfare nerve agents. We do not, at present, attach any special significance to the differences we have identified. More complete information on the potential exposures, the individuals affected, and research on the possible chronic health effects of low-level chemical warfare nerve agent exposures is needed. A copy of this compiled clinical data has been provided to the Committee.

The Persian Gulf Registry was never intended or designed to be a scientific research study. It is a health-care program which was established to assist veterans' entry into the continuum of VA care. As such, we encourage all Persian Gulf War veterans, symptomatic or not, to get a Registry examination. Furthermore, any Persian Gulf War veterans with health problems that may be related to an exposure that occurred during their Gulf service, is eligible for outpatient and inpatient care at VA medical facilities.

No Unique Syndrome

While some symptoms of Persian Gulf veterans are difficult to diagnose and remain unexplained, there is a general consensus among government and non-government physicians and scientists that current evidence does not support the existence of a single unique Persian Gulf Syndrome. The results of recently published research studies also has indicated that Persian Gulf veterans are not suffering at higher rates from life-threatening medical conditions or being hospitalized at higher rates than their non-deployed counterparts. Does this mean that there is no problem and that Persian Gulf veterans concerns are being dismissed or ignored by VA? The answer is an emphatic no.

Statements about the lack of a unique syndrome should not be misconstrued as being equivalent to a denial of the real illnesses, pain, and concerns of Persian Gulf veterans. Persian Gulf veterans who seek care from VA are suffering and, as indicated already, we are providing a substantial amount of health care and treatment for these veterans. Likewise, VA provides compensation for many of those who are disabled and is conducting research programs to better understand the nature and causes for their illnesses.

Possible Chemical Warfare Agent Exposures

The record shows that VA has always acknowledged the possibility that Persian Gulf War veterans were exposed to a wide variety of hazardous agents while serving in the Southwest Asia theater of operations, including chemical warfare agents.

In 1993, VA designed its clinical uniform case assessment protocol to detect clinical signs and symptoms related to possible nerve gas and other neurotoxic exposures. Neurologic examinations, neurophysiologic testing and cognitive testing were part of the earliest versions of this protocol. Because of this, appropriate diagnostic evaluations, care and treatment has been provided to Persian Gulf veterans despite lack of knowledge about verified chemical warfare exposures. After a thorough review of the evaluation protocol, I can confidently state that VA diagnostic protocols continue to serve as a valid set of clinical guidelines for initial screening examinations (Phase I) and more comprehensive evaluations of difficult-to-diagnose illnesses (Phase II) in Persian Gulf War veterans. These protocols received positive reviews by highly-respected physicians and scientists in the past. More recently, the Presidential Advisory Committee which was fully informed about the release of sarin at Khamisiyah, agreed with the Institute of Medicine's conclusion that the clinical evaluation programs of the VA and DOD are excellent for evaluation and diagnosis of Gulf War veterans' illnesses. In response to P.L. 103-446, the diagnostic protocol and program administration will be reviewed again by a newly constituted Institute of Medicine Committee which will meet for the first time on February 24 and 25, 1997.

There has been some confusion among veterans, families and other non-medical groups regarding these statements that medical care has not been negatively impacted and that the current protocol is valid despite the new knowledge regarding Khamisiyah. The key to understanding these statements is the recognition that, to date, no valid diagnostic test has been found to identify chemical warfare agent exposures that occurred years ago; therefore, no confirmatory test can be performed for veterans who wish to know whether or not they were exposed to these toxins during their service in the Gulf. In addition, neurologic examinations, neurophysiologic testing and cognitive testing were part of the earliest versions of this protocol. The treatments available are not exclusive or specific to damage from nerve agent exposures. The treatments are specific to symptoms or diagnoses rather than being dependent on cause.

In the wake of the recent information regarding possible release of nerve agents at Khamisiyah in March 1991, VA has been asked whether we listened to veterans who reported their belief that they had been exposed to chemical warfare agents during their Persian Gulf service. We believe that there is undeniable evidence that VA officials did listen to those veterans and did take appropriate action to investigate their concerns. As an example, members of a Navy Reserve Construction Battalion unit from Alabama, Tennessee, North Carolina, and Georgia reported suffering adverse health effects which they attributed to exposure to chemical warfare agents during their Persian Gulf War service. In response, in 1993 VA established a pilot medical program at the Birmingham VA Medical Center to evaluate their health status. As part of this special health-care program, more than 100 veterans were evaluated and treated. Veterans with cognitive symptoms received extensive (7-8 hour) neuropsychological testing and clinical evaluations. In 1995, Birmingham was designated as the fourth regional Persian Gulf Referral Center site in order to make this expertise available to a larger number of veterans.

Furthermore, the VA revised Registry examination protocol routinely asks participants to report the exposures they believe occurred during their service in Desert Shield and Desert Storm, including possible exposure to mustard gas or nerve agents. VA's openness to veterans' views and concerns is also evident in the representation of veteran service organizations on the VA Persian Gulf War Expert Scientific Advisory Committee ever since Secretary Brown established it in 1993. In addition to these clinical programs, research studies are underway to investigate the prevalence of symptoms and medical conditions among Gulf War veterans and to determine whether they are associated with the wide range of reported risk factors, including chemical warfare agents.

Research

In order to get the best assessment of the health status of the veterans, a carefully designed and well-executed research program is necessary. VA, as lead agent for federally

sponsored Persian Gulf War research programs, has already laid the foundation for such a research plan. Under the auspices of the Persian Gulf Veterans Coordinating Board's Research Working Group, VA has developed a structured research portfolio to address the currently recognized, highest priority medical and scientific issues. More than 80 research projects are in progress and others have been completed. We continue to search for answers and to expand our understanding of the complex array of issues related to Persian Gulf War veterans' illnesses. While scientific answers are being sought, VA also continues to provide Persian Gulf War veterans with needed health care and other services to reduce their suffering.

VA's own research programs related to Persian Gulf veterans' illnesses include more than 30 individual projects being carried out nationwide by VA and University-affiliated investigators.

VA established three Environmental Hazards Research Centers in 1994. All three centers are carrying out projects which address aspects of the potential adverse health outcomes of exposure to a wide variety of hazards, including neurotoxins. In 1996, we established a fourth center at the Louisville VAMC for investigation of adverse reproductive outcomes. In addition, VA's Environmental Epidemiology Service has completed an initial Persian Gulf Veterans Mortality Study and has begun a long-term mortality study. The VA National Health Survey of Persian Gulf Veterans and Their Families is being carried out by the VA's Environmental Epidemiology Service. Phase I, a postal survey of 15,000 Gulf War veterans and a comparison group of 15,000 Gulf era veterans, was completed in August 1996. The questions on this survey asked veterans to report health complaints, medical conditions, and possible exposures to a wide variety of possible environmental agents, including potential nerve gas or mustard gas exposure. The response rate for Phase I of this postal survey was good, with an adjusted response rate of approximately 57 percent. Phase II will consist of 8,000 telephone interviews and a review of 4,000 medical records. Phase II will address the potential for non-response bias,

provide a more stable estimate of prevalence rates for various health outcomes, and verify self-reported health outcomes in medical records. The Phase III examination protocol is being finalized and examinations of veterans and their family members are planned to begin in Spring 1997. Peer-review is provided by a subcommittee of VA's Persian Gulf War Expert Scientific Advisory Committee. Details of these and other government-sponsored research studies are included in the report, Federally Sponsored Research on Persian Gulf Veterans' Illnesses for 1995. Copies of this report have been provided to the Committee.

Coordinating Board

In January 1994, the President established the Persian Gulf Veterans Coordinating Board, chaired by the Secretaries of VA, DoD, and HHS, to provide interdepartmental coordination and direction of federal programs related to Persian Gulf War veterans. The Coordinating Board provides an interdepartmental means to share information on Persian Gulf War veterans health, to allocate available resources to the apparent highest priorities, and to disseminate new research information. The Coordinating Board has three specific objectives:

- to ensure that Persian Gulf War veterans are provided the complete range of health care services necessary to take care of their medical problems that may be related to deployment in the Gulf;
- to develop a research program that will result in the most accurate and complete understanding of the health problems experienced by Persian Gulf War veterans and the factors that have contributed to these problems; and
- to develop clear and consistent guidelines for the evaluation and compensation of disabilities related to Persian Gulf service.

VA plays a central role in the Persian Gulf Veterans Coordinating Board through its participation in the Clinical, Research, and Compensation and Benefits Working Groups. In particular, the Research Working Group provides guidance and coordination for VA, DoD and HHS research activities related to Persian Gulf War veterans' health. It coordinates all studies conducted or sponsored by these three departments in order to prevent unnecessary duplication and to ensure that important gaps in scientific knowledge are identified and addressed. The working group is actively involved in directing resources toward high priority questions and monitoring the results of federally sponsored research projects. It has produced two reports: Federally Sponsored Research on Persian Gulf Veterans' Illnesses for 1995 and the 1996 update of A Working Plan for Research On Persian Gulf Veterans' Illnesses.

One example of the Coordinating Board's proactive role in relevant research administration was its prioritization of the federal government and non-government research proposals submitted for funding pursuant to DoD's 1996 Broad Agency Announcement. The American Institute for Biological Sciences (AIBS) performed peer-review of the 111 proposals submitted. The research working group reviewed those proposals judged scientifically meritorious by AIBS and prioritized them according to relevance and potential to fill research gaps in the existing Persian Gulf research portfolio. Twelve research projects encompassing the areas of reproductive outcomes, toxicology of pyridostigmine bromide, modeling of respiratory toxicant exposures from tent heaters, neuropsychological outcomes, immune dysfunction, mycoplasma infection, leishmaniasis, chronic fatigue, fibromyalgia, and neuromuscular function were given high priority for funding by the research working group.

Studies of the potential long-term health effects of low-level (asymptomatic) chemical warfare agent exposure were not given a high priority in the 1995 Working Plan or other research questions because military and intelligence sources had stated that there had been no use, presence, or evidence of exposure to chemical warfare agents in the theater of operations. Based on these statements, combined with a lack of clear-cut

clinical evidence to support a finding of chemical warfare exposure, the Coordinating Board focused its research resources on other questions. However, while exposures per se were not a focus of research, clearly the health outcomes which could result from such a neurotoxic exposure were given priority. These outcomes included cognitive, neurologic, and neuromuscular effects. This decision was supported by committee reports from the Institute of Medicine, VA Persian Gulf Expert Scientific Committee, the National Institutes of Health Technology Assessment Workshop, the Presidential Advisory Committee on Gulf War Veterans' Illnesses, and others.

When DOD made its June 1996 announcement regarding possible exposure of U.S. troops to sarin and cyclosarin as a result of the demolition at Khamisiyah, the Coordinating Board immediately began revision of its action plan. Through the Research Working Group of the Coordinating Board, VA in conjunction with DoD and HHS has developed an action plan to address possible long-term health consequences of low-level exposure to chemical warfare nerve toxins and mustard gas.

A recent literature review carried out by independent, non-government and government scientists, suggests that readily-identifiable, long-term adverse health effects due to nerve agent exposures seem to only occur in humans who show signs of acute toxicity or poisoning. However, I should note that the research in this area is sparse and the absence of proof is not proof of absence. In VA's judgment, this information does not mean that clinically important adverse health effects cannot or definitely do not occur in the setting of low-level neurotoxin exposures, especially if combined with other components or environmental stressors. The Coordinating Board has recommended that more research resources be allocated to address this question. I strongly agree with this approach. The Research Working Group has reconsidered the matter and intensified its efforts related to possible effects of low-level exposures to chemical warfare agents.

Based on the Coordinating Board's recommendation, the newest recommendations from the PAC regarding investigations of the potential chronic health effects of low-level chemical warfare agent exposures, physiologic effects of non-traumatic and traumatic stress and the effects of pyridostigmine in combination with other exposure agents, have already been incorporated into the Coordinating Board's latest Working Plan for research and requests for proposals were published by DoD. Funding for these new efforts will come from the DoD's appropriation. A copy has been provided to the Committee.

While these efforts represent a good beginning, VA's Research Service is taking a fresh look at these issues in light of the new information provided by DoD. This includes developing a strategic plan for an environmental health research agenda that specifically focuses on low-level exposures to neurotoxins that might result from chemical warfare agents or other military situations. Likewise, we have organized an international scientific symposium in March 1997 that bridges potential military and civilian incidents involving exposure to those types of chemicals. Given the relative lack of worldwide scientific capability for assessing these issues in the traditional open and peer-reviewed manner in which the best science is carried out, we believe it is essential to bring together a multi-disciplinary group of experts to focus on finding innovative solutions to these perplexing issues.

Research related to the illnesses of Persian Gulf War veterans is highly complex, and this is especially so for the investigation of concerns related to possible low-level exposure to chemical warfare agents. VA is committed to meeting these challenges and obtaining the most accurate answers we can concerning the health of PGW veterans and their families. The recently submitted final report of the Presidential Advisory Committee on Gulf War Veterans' Illnesses will be particularly useful in this regard.

New Initiatives and Continuing Education

VA has been proactive in establishing health-care programs for Persian Gulf War veterans. In the immediate post-war period, the medical and scientific community had

only limited knowledge of the complexity of Gulf War specific issues and exposures. Through our clinical and research programs, VA has been a leader in the development of health care programs, improvement of understanding concerning PGW health issues and dissemination of knowledge on Gulf War-related health issues. We believe that our programs are well-designed and comprehensive, but are neither uniformly delivered nor perfect. We also recognize that some Persian Gulf veterans have not received the kind of reception or care at VA medical facilities that we can be proud of. To those Persian Gulf veterans, I want to assure you that the Veterans Health Administration (VHA) is working diligently to improve your satisfaction with our services. VHA has established quality monitors and performance standards for the Registry program and is developing a new customer satisfaction survey for Persian Gulf veterans.

I am also very pleased to announce today that we are establishing a Service Evaluation and Action Team (SEAT) within each Veterans Integrated Service Network. These programs will allow us to collect data for quality improvement of our programs and to further our goal of providing the highest quality care to veterans.

In order to keep our health-care providers well-informed on the latest developments, VA has utilized a wide array of communication vehicles including periodic nationwide conference calls, mailings, satellite video-teleconferences and annual on-site continuing medical education (CME) conferences. Our initial efforts were successful in educating a dedicated cadre of well-informed Registry physicians and staff, and we will continue to keep them up-to-date on the latest developments. However, I see an opportunity to improve the understanding of Persian Gulf war-related health issues by other medical personnel. My goal is that all VA health-care providers will have a working understanding of Gulf War exposures and health issues and will be able to discuss with their Persian Gulf patients how these issues could impact on their current or future health status. In order to meet this challenge and continue to improve our programs, the Veterans Health Administration has developed and will publish a self-study Persian Gulf CME program for every VA physician in early 1997. We will make this available to non-VA physicians, at cost, as well.

The Presidential Advisory Committee found that our Registry and Referral Center personnel were indeed knowledgeable and well-informed about all aspects of Persian Gulf veterans' health issues. However, education of health care providers not directly involved in the Registry program and VA's risk communication efforts should be enhanced and augmented. VA agrees and these efforts are already under development.

Compensation Programs

In addition to the vast array of medical programs available to Persian Gulf veterans, we also have a special provision of law governing compensation for undiagnosed illnesses. On November 2, 1994, the President signed Public Law 103-446. VA strongly supported this legislation to allow us to pay compensation to any Persian Gulf veteran with a chronic disability resulting from an undiagnosed illness or combination of undiagnosed illnesses that appeared either during active duty in the Persian Gulf or to a degree of disability of 10 percent or more within a presumptive period thereafter. In the regulation implementing this statute, we established a two-year presumptive period.

Public Law 103-446 required VA to determine an appropriate presumptive period following a review of the credible scientific and medical evidence and the historical treatment afforded disabilities for which manifestation periods have been established, and taking into account other pertinent circumstances regarding the experiences of veterans of the Persian Gulf War. Although many veterans began to develop unexplained signs and symptoms of illness shortly after their return from the Persian Gulf, there was (and is as yet) little or no medical evidence definitively linking the illnesses with service in the Gulf. Given the uncertainty of available scientific and medical evidence, we felt that a presumptive period could not be established on this basis, and we looked at the other two factors, historical treatment and pertinent circumstances, to determine an appropriate period. We found a one-year presumptive period, as has been historically provided for various chronic diseases, was inadequate in the case of Persian Gulf veterans due to the lack of awareness of the potential significance of their symptoms upon their return from

the Gulf. Further, VA did not begin full-scale operation of its Persian Gulf Health Registry until November 1992. Because many Persian Gulf veterans first presented their health concerns in connection with VA's Persian Gulf Health Registry examination, veterans of the hostilities, who began to return from the Gulf by mid-1991, did not have this resource available to them within the first year following their return from the Gulf. We believed, however, that within two years after leaving the Gulf all veterans of the hostilities would have had this opportunity to document their illnesses.

There have been growing concerns, expressed by members of Congress and the veteran community, that the two-year presumptive period for undiagnosed illnesses may no longer be appropriate. Some veterans are reporting even now that they are experiencing for the first time unexplained illnesses that they believe are related to their service in the Persian Gulf. Because of these concerns, the Secretary recommended to the President in early January that the issue of the presumptive period be revisited. On January 7, the President announced that he had approved this recommendation and asked Secretary Brown to report back to him in 60 days.

During this 60-day period, the Secretary will gather as much information as possible from veterans, veterans' service organizations, Members of Congress, and VA officials. As part of that effort he has written to each of you to solicit your views. The Secretary also has planned a series of forums to obtain input directly from those veterans who would be affected by a change in the presumptive period. One forum was held at the Milwaukee Regional Office on February 7, and five additional forums are planned for later this month in Muskogee, Cleveland, Montgomery, Oakland, and Winston-Salem. The Secretary will also take into account information from the ongoing readjudication of approximately 11,000 Persian Gulf cases.

The Secretary will provide advice to the President with regard to extending the presumptive period by March 8, 1997. If a determination is made that a modification to

the presumptive period is warranted, we will prepare regulations to implement that decision as soon as possible. If a new presumptive period is established, we will also conduct a further review of the undiagnosed illness cases we already have on hand in order to identify those in which service connection can be granted because of the longer period.

Persian Gulf veterans are not faceless statistics to VA health care personnel. They are individual American citizens who have answered their country's call to arms and served their nation bravely. They are individuals who come to us with genuine problems and concerns for their future. Our doctors, nurses, therapists and directors are dedicated to providing compassionate care, compensation examinations and answering medical question. We will push forward with our programs. If we fall short of the high standards we set for ourselves, we will strive harder to achieve our goal of continuous improvement. President Clinton has made it clear that no effort should be spared in this regard. In the end, long after the headlines fade away and national attention turns elsewhere, VA will still be there to care for Persian Gulf veterans. It is our mission. It is our nation's irrevocable promise to its veterans.

In this regard we are grateful for the assistance provided by the Presidential Advisory Committee on Gulf War Veterans' Illnesses. We recognize the central role they played in investigation of possible troop exposure to sarin and cyclosarin. The recommendations released in the Committee's final report will be given serious consideration. As the President has directed, VA along with the Defense and Health and Human Services Departments will be preparing an action plan addressing the Committee's recommendations. This action plan, which will be developed by the Coordinating Board, will be presented to the President within 60 days.

That concludes my statement. My colleagues and I would be happy to answer any questions you may have.

Persian Gulf Illnesses

Statement by

STEPHEN C. JOSEPH, M.D., M.P.H.
ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

Before the

Committee on Veterans Affairs
U.S. House of Representatives

First Session, 105TH Congress

February 11, 1997

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COMMITTEE ON VETERANS AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

Mr. Chairman, Distinguished Committee Members, thank you for this opportunity to review with you the Department's health initiatives for our Persian Gulf veterans. President Clinton promised that we would explore all avenues for understanding the Gulf War illnesses; that we would take care of the veterans who believe their Gulf War experience has resulted in a degradation of their health; and that this Administration would put its resources into scientific research to find explanations for these illnesses. We have been doing just that, and we will continue to do so.

My testimony will specifically address the Department's programs caring for our Persian Gulf veterans, and which seek to find scientific answers to their health problems.

It is important to briefly trace the growing awareness of Gulf War Illnesses and the programs DoD has undertaken to address them. The Gulf War had been over for two years when the Clinton Administration took office. In that period, the voices of Gulf War Veterans who were experiencing a variety of symptoms believed to have been a result of their service in the Gulf War, reached the national level of hearing and concern. President Clinton promised that his Administration would help the veterans of the Gulf War, and the Congress echoed that promise to ensure help and to find answers.

Comprehensive Clinical Evaluation Program

In Defense, our most immediate concern was, and is, to help those Gulf War veterans who are sick to regain their health. With that as our primary goal, and with strong support from the Secretary of Defense, on May 11, 1994, I announced a three-point plan to address the clinical concerns of Gulf War veterans. The plan included first, an aggressive, comprehensive, standard, clinical diagnostic program offering thorough, systematic examinations and follow-on health care to service members who served during the Gulf War and who had concerns about possible health consequences of that service. This program is titled the Comprehensive Clinical Evaluation Program (CCEP), and very closely parallels the clinical evaluation program of the Department of Veterans Affairs (VA). In developing the evaluation protocol and series of tests to be conducted, we felt it imperative to retain an open mind regarding potential causes, including chemical warfare agent exposure. For that reason, a broad spectrum of tests comprise the CCEP, including neurologic examinations and cognitive testing. Upon completion of the CCEP evaluation, an appropriate course of treatment is initiated and followed for each participant when medically indicated.

Since 1994, the DoD leadership, without precedent, reached out to service members to encourage them to participate in the CCEP. Outreach efforts continue, significantly strengthened by the efforts of Dr. Rostker and his staff. Addressing the health concerns of our Gulf War veterans, our outreach includes direct correspondence with service members; meetings with numerous organizations representing Gulf War veterans; speaking, at their request, to gatherings of veterans; and conducting numerous media interviews to continuously update the veterans on what we were learning through the CCEP and medical research. Our openness on Persian Gulf Illnesses marks a great contrast to previous experiences, such as Agent Orange.

Also in the spring of 1994, we initiated the second element of our three-part plan: an independent evaluation by an individual with recognized credentials in the fields of epidemiology and infectious disease. This was to examine the Department's existing and proposed plans pertaining to Persian Gulf Illnesses and to recommend additional epidemiological studies.

The independent evaluation was conducted by Dr. Harrison Spencer, then Dean of Tulane School of Public Health and Tropical Medicine. Doctor Spencer recommended that DoD continue with the comprehensive diagnostic program, that the frequency of unexplained illnesses among different groups that had been reported be estimated, that care not be dependent upon establishment of a "case definition," that testing for clustering of reported symptoms in time and space be considered, and that the Department develop a strategy to manage similar situations in the future. Each of Doctor Spencer's recommendations has been accomplished or is underway.

Finally, the three-part 1994-plan called for a forum of national medical and public health experts to advise the Department and to offer a channel for broader public comment and suggestions.

The Institute of Medicine of the National Academy of Sciences, under contract to DoD, established an advisory committee composed of ten clinical experts in the fields of internal medicine, infectious diseases, allergy and rheumatology. This committee assisted in the interpretation of the clinical findings from the comprehensive diagnostic examinations of the CCEP and advised on other clinical studies that the Department should pursue. The Institute of Medicine continues to assist us as an independent panel of experts monitoring our efforts and advising us on specific issues or questions.

The evaluations and care of our Persian Gulf veterans continue. To date, over 38,500 are on the DoD registry. Through the CCEP, over 25,000 individuals have been extensively examined, with about 4,000 in the process of evaluation. As the CCEP participants complete their evaluations, military physicians develop appropriate treatment regimens to ensure their patients receive the care they need to regain their health. Not all Gulf War veterans who wish to be on the DoD registry want to have the CCEP evaluation; just over 9,000 have placed their names on the registry, but declined the evaluation. The VA registry has over 63,000 individuals who have completed the evaluation and about 3,700 who are in the process of being evaluated.

Looking at the results of the evaluations of those who participated in our clinical evaluation program, we identified several findings. CCEP participants report a wide variety of symptoms spanning multiple organ systems in no consistent, clinically apparent pattern. Symptoms such as fatigue, joint pain, headache, or sleep disturbances are common. The distribution of primary diagnoses spans many different organ systems. The majority of CCEP participants have diseases which are concentrated in three broad diagnostic groups: "psychological conditions;" "symptoms, signs, and ill-defined conditions;" and, "musculoskeletal and connective tissue diseases;". In each of our in-depth analyses of the CCEP -- at the 1,000, 2,000, 10,000, and 18,500 case points -- the results were similar. Our efforts within the Department to care for the Gulf War veterans have reinforced to us the seriousness of their health

complaints, and our military physicians fully recognize that these veterans are experiencing real symptoms and illnesses with real consequences.

One of most striking findings of our clinical work has been the recognition of psychological conditions and stress-related symptoms as a major diagnostic category among veterans cared for in our facilities. Our clinicians have been impressed that stress experienced during the Gulf War and in its aftermath appears to be a major contributing factor in the development of psychological conditions as well as the manifestation of symptoms associated with non-psychological conditions. This observation is consistent with the findings of special review panels of the National Institutes of Health, Institute of Medicine and Presidential Advisory Committee on Persian Gulf Veterans' Illnesses. We agree with the PAC finding: "Stress is known to affect the brain, immune system, cardiovascular system, and various hormonal responses. Stress manifests in diverse ways, and is likely to be an important contributing factor to the broad range of physiological and psychological illnesses being reported by Gulf War veterans."

Our Persian Gulf veterans deployed prepared for war. Once in the Gulf, they endured a daily anticipation of hostilities including possible chemical warfare, austere living conditions and indefinite family separation. For some, the waiting continued for six months. It was a period, a place, an environment conducive to anxiety and stress.

Our CCEP clinical experience to date reveals no evidence for a single, unique illness or syndrome. A unique illness or syndrome among Persian Gulf veterans evaluated through the CCEP, capable of causing serious impairment in a high proportion of veterans at risk, would probably be detectable in the population of over 25,000 evaluated. However, we agree with the IOM, which cautioned that an unknown illness or a syndrome that was mild or affected only a very small proportion of veterans at risk might not be detectable in a case series, no matter how large.

Formal research involving appropriate comparison populations is necessary to determine the degree to which certain kinds of symptoms or diagnoses may, or may not, be more common among Gulf War veterans. We have that research underway. Further, in an unprecedented step, we have made the CCEP database --with appropriate privacy precautions taken -- available to scientists interested in conducting additional analyses. To gain access to the database, scientists are encouraged to submit an institutionally approved protocol which may be done electronically via the Internet. Guidance on how to accomplish this is on the DoD Health Affairs Homepage. Once the request process has been completed, the database is made available.

Persian Gulf Illnesses Research

Let me turn now to a discussion of our health research programs. Quality scientific investigation, in parallel with the clinical program, broadens efforts toward a more complete understanding of the health issues related to service in the Persian Gulf War. Our research efforts are proceeding at a rapid pace with extensive openness and breadth of evaluation. However, quality scientific investigation is deliberate and does take time. It is very important to note that DoD's research program is conducted with extensive collaboration with the Departments of

Veterans Affairs and Health and Human Services. Our interagency collaboration extends to scientists from the civilian research community, to state and other federal scientists, as well as to respected international scientists.

The Departments of Defense, Veterans Affairs, and Health and Human Services, through the Persian Gulf Veterans' Coordinating Board, have established a comprehensive research program concerning Persian Gulf illnesses. This research is complex, involving multiple approaches and health indicators. Although each Department has its own distinct capability and capacity for conducting formal scientific medical research, the three Departments have developed an integrated research approach. The objective is to coordinate all federally-sponsored research in a way that relevant research issues are specifically targeted and at the same time, unnecessary duplication is avoided.

Since the earliest days of seeking explanations for the causes of Persian Gulf Illnesses, we have acted on the recommendations of the IOM and, later the Presidential Advisory Committee. We have required that all research be externally peer-reviewed and thoroughly coordinated with the Persian Gulf Veterans Coordinating Board.

To demonstrate our commitment to the research effort, the Deputy Secretary of Defense has pledged \$27 million for FY 97. This research responds to the recommendations of the Presidential Advisory Committee, and will include studies of chemical warfare agents, as I mentioned above, other toxins, and studies of possible health effects of combinations of inoculations and investigational new drugs; it will include studies on the potential health effects of stress. Other research included in this will be work on the geographic information system, toxicology clinical investigations, mycoplasma, sleep disorders, infectious diseases and fibromyalgia. Additionally, the series of 7 large scale epidemiology studies underway at the Naval Health Research Center are included.

Action Steps as a result of Khamisiyah

When we became aware that the Khamisiyah demolition operation had the potential of chemical exposure for units operating in and around that area in March 1991, I immediately issued instructions for additional measures to assess specific health implications.

a. The first step was to review the clinical records of service members from the involved units who had participated in our CCEP. A team of three military physicians and then a team of two independent physicians accomplished this step. There are 46 members from these units who participated in the CCEP. Our intent was to get some initial insight as to whether or not any serious health problems may be present. The patterns of reported symptoms and diagnoses did not differ significantly from other groups of CCEP participants. While not definitive, the findings of the review provided us reassurance to proceed in a prudent manner and convey risk without alarming veterans unnecessarily.

To date, we have identified 1,194 CCEP participants out of about 20,000 service members from Army units which were within 50 kilometers of Khamisiyah. We have conducted

preliminary descriptive analyses to determine how their reported symptoms and diagnoses compare with other Army CCEP participants who were not present in the Khamisiyah area. Interpretation of such analyses is limited because of the relatively small numbers of CCEP participants in the Khamisiyah group identified to date, uncertainty regarding the exact location where members may have served, and differences in the demographic and occupational characteristics of the Khamisiyah group compared against any other group within the CCEP. Preliminary results indicate that the frequencies of self reported symptoms of the CCEP participants identified as having served within 50 km of Khamisiyah are similar to other Army CCEP participants. Additionally, the distribution of primary diagnostic categories of the Khamisiyah group is similar to that of other Army CCEP participants. We plan to do further analyses.

b. The second step was to contact individuals who were assigned to the involved units to inform them of the known details, to confirm their unit locations, and to remind them of the availability of medical evaluations through the CCEP or Department of Veterans Affairs program. This has been accomplished.

c. Next, we conducted a review of information regarding DoD hospitalizations since the Persian Gulf War, accumulated by the Naval Health Research Center, to identify any unusual patterns involving members of these units. Results to date reveal no unusual hospitalization patterns.

d. The Armed Forces Epidemiology Board (AFEB) conducted a comprehensive literature review and critique regarding the issue of chronic or delayed health effects resulting from low-level exposures to chemical agents. The Board completed a review of scientific, peer-reviewed works, and found virtually no research linking chronic or delayed health effects to prior low-level exposure to chemical agents, in the absence of acute clinical effects. An important aspect of this review is that it focused on scientific, peer-reviewed works. Because the body of research is not substantial, more research is needed and will be funded.

e. The Department established as a top priority and rapidly funded expedited peer-reviewed research concerning the subject of potential chronic health effects caused from low-level exposures to chemical agents. Three research proposals, external to the Department, have been funded for a total of \$2.5 million. Additional research is under consideration and includes targeted epidemiological, applied toxicological, and clinically related studies.

f. Finally, I asked the Institute of Medicine to re-examine our CCEP to determine if, in light of the Khamisiyah information, DoD should again evaluate some individuals or conduct further tests.

There were no chemical casualties reported during any of the demolition operations at Khamisiyah. An evaluation of medical logs of units in the area did not show any increase in clinic visits or any reports of chemical exposure symptoms. With that lack of clinical evidence and no physical evidence to substantiate that chemical agents were present, the Department turned its attention to the question of whether there might have been very low (below detector sensitivity)

levels of chemical agents present. Preparing to look for whatever evidence there might be, the scientific evidence on consequences of possible exposure to very low levels of chemical agent was reviewed first. Very little was found to direct the investigation.

To date, no controlled human studies have been found in which measured doses, designed to avoid symptoms, were utilized, and subjects monitored over extended periods of time. However, reasonable extrapolations can be made from two controlled human studies, a few accident investigations, and several animal studies, all of which, however, involved exposure at levels sufficient to produce symptoms.

Some of these studies were described to the Presidential Advisory Committee on Gulf War Veterans' Illnesses. These included the largest controlled study known, lasting over decades, finding no long-term (over years) effects from short-term low-level exposure to chemical warfare agents. The second controlled study was one in which acute symptoms were produced in volunteers. Cholinesterase levels were examined, but no long term follow up was done on the subjects.

The controlled studies were complemented by studies which included large numbers of inadvertently exposed personnel as well as individual exposures. In general, the accidental exposure patients, where the individual initially showed acute symptoms, were followed through short-term recovery periods. At the end, the EEGs of some subjects showed non-specific changes, but the individuals exhibited no other symptoms. Long-term follow-up (over years) was not reported in the accidental exposure studies.

Many animal studies have been done, but very few involved low level chemical agents. To date we have not been able to identify human or animal studies that have directly addressed the issue of short term low level nerve agent exposure followed by chronic symptomatology or disease. The existing literature, though limited, consistently indicates that in humans and animals receiving short-term exposure to agent levels which do not produce symptoms, no long-term (months to years) clinical effects are found.

The limited amount of research on low level exposure has caused us to initiate more research into this area.

Presidential Advisory Committee Recommendations

The Presidential Advisory Committee on Gulf War Veterans' Illnesses (PAC) provided substantial thought, important findings and very constructive recommendations throughout its process and in its final report. Consistent with the Committee's recommendations, we will submit an action plan outlining the steps, including those already partially or fully implemented, being taken by the Department. Let me give you a sense of what steps we have taken, or that we expect to take.

1. DoD will collaborate with other federal agencies to refine goals and objectives and develop more effective methods for risk communication regarding Gulf War veterans'

- illnesses. In the interests of both providing Gulf War veterans with health related information and receiving feedback on DoD health programs, DoD will engage active duty personnel, including senior enlisted personnel, and veterans' service organizations, working with VA, in the process of information exchange.
2. DoD strongly agrees with the importance of pre-deployment health assessment. The Department is developing a medical surveillance policy for deployments which specifies a uniform concept for health screening. This policy was partially implemented in Bosnia and is being fully implemented for Southwest Asia. We expect the new medical surveillance policy to be formally adopted during 1997.
 3. DoD already does some orientation and training for new troops on the chemical and biological threat and on the counter measures which may be needed. More needs to be and will be done. The goal of DoD is that every Service member is fully informed during orientation and training of the health risks, benefits, and proper use of all medical countermeasures, and, when used, documented and maintained as a part of the individual's health record. Given the potential for serious chemical and biological threats for future conflicts, both using countermeasures and having our Service members fully informed are critical to effectively protecting them.
 4. DoD agrees with the need for FDA to solicit timely public and expert comment on rules that permit waiver of informed consent for use of investigational products in military exigencies. DoD intends to work with FDA on ways to more expeditiously process such rules in order to ensure that we have effective countermeasures to deal with existing and new chemical and biological warfare threats. DoD agrees that, to the full extent feasible, there should be disclosure to Service personnel, good record-keeping, and other procedures which enhance understanding, oversight and accountability.
 5. DoD continues to actively develop an automated medical records system that is used during deployments and when Service members are at their home base health facilities. Major portions of that system are already being used in Bosnia. Further refinements, including the addition of an automated patient record and "meditag" record, are being made as quickly as is feasible. These systems will be compatible with the records systems being used worldwide.
 6. The Department will review the clinical staffing needs required to satisfy Gulf War veterans' health needs, including mental health, and ensure that those staffing needs are met. With respect to future deployments, the Department has in place its Comprehensive Clinical Evaluation Program, including support to all military treatment facilities, to assist with the evaluation and care of illnesses that may result from those deployments and are difficult to diagnose.
 7. DoD provides reproductive health care for its Service members and their families and has made reproductive health concerns a higher priority for all beneficiaries in their reproductive years. Currently, the Department is putting into place performance metrics to better assess reproductive health outcomes and the associated health care and to assist in the overall management of that care. Special efforts are being made for Gulf War veterans in the areas of evaluation and care and epidemiological and other research.

8. DoD is currently writing a DoD Directive which addresses the recognition and management of combat stress. When this policy directive is published, the Services will be expected to publish implementation instructions within 120 days. These instructions will focus on stress reduction programs particularly for deployed troops. Meanwhile, special combat stress coping units have deployed to Bosnia and conduct critical incident stress debriefings for catastrophic incidents that occur in the Services. Through the forthcoming Directive on Combat Stress, DoD will set the policy to have senior commanders and non-commissioned officers be involved in stress management programs.
9. Principal Investigators (PI) conducting large epidemiologic studies have been encouraged to establish Public Advisory Committees (PACs). Future Requests for Proposals will require PIs to incorporate PACs into the study design and results dissemination phases of the research.
10. DoD has initiated several new research studies and recently published a Request for Proposals specifically addressing the health issues of sub-clinical or low level exposures to chemical warfare agents. We are asking the scientific community to help us determine what mix of human population and animal model studies will provide the best understanding of this complex issue.
11. DoD agrees that long term mortality follow-up studies are important and should be funded.
12. DoD initiated an effort in the fall of 1996 to identify, verify and notify Service members who were within a 50km radius of the Khamisiyah weapons demolition site during the demolition operations. Any of these Service members who are ill or have health concerns have been encouraged to sign up with the DoD Comprehensive Clinical Evaluation Program for evaluation and care or the VA Persian Gulf Health Registry for evaluation. In order to better understand any relationship between the demolitions, potential exposure and subsequent illness, DoD and VA are carrying out epidemiological studies and funding research. For any other sites which are identified and for any other Service members who may have been exposed in these cases, similar steps will be taken with respect to notification, evaluation, care, and research as for Khamisiyah.
13. DoD agrees that research on causes and methods of prevention and treatment of musculoskeletal conditions and stress disorders are important areas for investigation. In funding future research, DoD will look for opportunities which would increase understanding of causes, prevention and treatment of these health problems.

At this time, in collaboration with the Departments of Veterans Affairs and Health and Human Services, we are finalizing the response to the PAC and plan to submit it to President Clinton shortly.

Implications for the Future

The CCEP protocol and process represents a new and innovative system to evaluate the health status of service members who participate in operational deployments, such as in Bosnia and others in the future. Modification of our policies and processes will allow the Department to

administer health questionnaires and conduct medical examinations of groups of deployed personnel, and collect the information through an automated process for entry into a centralized database for subsequent analysis and interpretation.

The Department's experiences with the Persian Gulf War illnesses indicate that there are initiatives which can be implemented today to better provide for our service members in the future. Among those initiatives is the Medical Surveillance Program.

Medical Surveillance Program

More than a year ago, the Department embarked on an ambitious program to expand its capability to conduct medical surveillance to monitor the health and well being of men and women in uniform, especially in situations where they deploy to hazardous areas in the interest of national security, as they are presently doing in Bosnia. Medical surveillance involves the ongoing systematic collection, analysis, and interpretation of health data for use in preventing and controlling illnesses and injuries. Today, the Department is in a better position to protect the health of the force as a result of progress made in promoting an expanded concept of medical surveillance, and placing strong emphasis on the readiness posture.

A number of "lessons learned" have emerged following Operations Desert Shield/Storm which have provided the impetus for many medical surveillance initiatives. The Department takes pride in the fact that the Gulf War was associated with a lower disease and non-battle injury (DNBI) rate than any major conflict in U.S. history. However, the inability to resolve uncertainties regarding long term, chronic health sequelae of veterans is due in part to a deficiency of objective measures of individual health status at the time of deployment and exposure information needed to evaluate potential health risks. These observations have led to major changes involving health screening, exposure assessment, risk communication, and assessment of health outcomes after deployments. Clearly, essential medical surveillance functions must be continuous and fully integrated throughout pre-, during, and post-deployment phases of military operations.

We are in the final stages of coordinating this new medical surveillance policy, major elements of which have already been implemented in Bosnia. The policy focuses on ways to better define and document the deployed population, their unique exposures, countermeasures used to protect the force, and health outcomes as a result of the deployment. The policy describes an integrated framework for monitoring the physical and psychological health of the deployed force and includes the following major components:

- Establishment of personnel databases which serve as registries of deployed service members
- Development of uniform educational materials which communicate health risks associated with deployment
- Standardized health screening during pre- and post- deployment phases
- Deployment of laboratories with advanced analytic capabilities to assess health hazards and document exposures

- Deployment of preventive medicine teams to assess all aspects of disease and environmental threats; establish geographic-specific medical surveillance systems; investigate disease outbreaks; implement preventive medicine measures; and, document environmental and combat exposures.
- Deployment of combat stress management teams to maintain optimal combat effectiveness, unit morale and cohesion
- Collection of serum from deployed personnel for possible use for diagnostic purposes, and/or epidemiologic purposes
- Psychological screening of personnel post deployment
- Promotion of family advocacy and other related programs to provide assistance to service members upon re-deployment to their home station

The Department's enhanced medical surveillance approach will evolve further in response to new and emerging health threats and assessment of lessons learned from actual application of surveillance concepts in military operations.

In summary, our strategy towards developing an integrated medical monitoring program for deployments involves multiple components. Our experience in providing care to Persian Gulf War veterans has provided clinical insight into the types of medical problems that may arise from the stressful physical environment and psychosocial demands of operational deployments. The deployment to Bosnia provided an opportunity to field test the feasibility of new concepts regarding pre-, during, and post-deployment medical surveillance activities. In addition, multiple Persian Gulf related research studies are in progress or being planned, the results of which may identify new areas requiring preventive intervention. Research findings will be merged with clinical and operational experience to further refine medical surveillance programs.

The Department is making significant progress in expanding its capability to assess the health status of personnel prior to deployment, evaluate environmental hazards in a theater of operations, and identify adverse health outcomes which may result from their participation. The surveillance reflects careful consideration of recommendations from a variety of sources including:

Consultation provided by Dr. Harrison C. Spencer,
National Institute of Health Technology Assessment Working Group,
Defense Science Board, Task Force On Persian Gulf War Health Effects,
Institute of Medicine, Committee On The DoD Persian Gulf Syndrome, and
Presidential Advisory Committee on Gulf War Veterans' Illnesses.

Closing

Many actions are still in progress. Nevertheless, the Clinton Administration rapidly and effectively created a comprehensive, well-organized, cross-departmental program designed, first and foremost, to take care of service members. Further, there is strong commitment to pursuing the science and using investigative tools to find answers to remaining questions. The President reaffirmed his commitment by retaining the Presidential Advisory Committee on Gulf War Veterans'

Stephen C. Joseph

HVAC/PGI, 2/11/97

Illnesses to ensure that everything possible is being done to understand the health consequences of service in the Persian Gulf.

The Department's clinical and research efforts will continue. As President Clinton has vowed to leave no stone unturned in the search for answers to Persian Gulf War veterans' health concerns, we are committed to providing quality, compassionate care to service members who are Persian Gulf veterans and to their families, and to conducting the appropriate research to gain greater understanding of these issues.

Like the Presidential Advisory Committee, we recognize that the issues surrounding Gulf War illnesses are very complex. Since the end of the Gulf War, concerns have been raised as to whether there is a relationship between illnesses being experienced by some Gulf War veterans and their family members, and exposures to various hazards during Gulf War service. These concerns are of particular importance to our Gulf War veterans and their families. We share these concerns, and continue taking unprecedented steps to determine the causes of these illnesses and to provide care for those who are ill.

Statement by Dr. Bernard Rostker, Special Assistant to the
Deputy Secretary of Defense for Gulf War Illness
Before the House Veterans Affairs Committee
11 February 1997

Mr. Chairman. Thank you for the opportunity to appear before this committee. As you know, the Deputy Secretary of Defense, Dr. John White, appointed me Special Assistant for Gulf War Illnesses on November 12, 1996. The action was part of a broader set of initiatives undertaken on September 28, 1996, to assess the Department of Defense's Gulf War Illnesses program in view of recent events, to include the reports that soldiers may have been exposed to chemical agents during the destruction of the storage site at Khamisiyah.

As The Special Assistant, my first priority is the health and welfare of our Gulf War veterans. In this capacity, I serve as the DOD coordinator for all issues relating to Gulf War. I see the Gulf War Illnesses mission has three parts. First, to ensure that all who served in the Gulf War receive appropriate medical care; second, that DOD does its part to ensure that we conduct a complete and thorough investigation to determine why so many of our veterans are ill; and third, to apply our findings to future deployments.

Two vital aspects of this mission are to ensure that we learn everything possible about the potential causes of illnesses, including events during and after the Gulf War and to promote improved communication with Gulf War veterans on the relevant health care issues. This endeavor is critical because we have a moral duty to our veterans and to those who serve now. Therefore, we must understand what is making our people sick so that we can make the changes necessary to protect our people in the future. Our efforts here must have long-term effect. We must ensure that DOD puts into place all required military doctrine, personnel and medical policies, procedures and equipment to

prevent future recurrence of the problem and we must work cooperatively with VA to coordinate all issues critical to their program responsibilities.

The guidance from President Clinton is clear: "I want to assure all of you that we will leave no stone unturned in our efforts to investigate Gulf War illnesses, and to provide our Gulf War veterans with the medical care they need. There are mysteries still unanswered and we must do more." I will make it my business to leave no stone unturned.

To carry out this important task entrusted to me by the Deputy Secretary of Defense, I have expanded by an order of magnitude the Department of Defense's investigations organization. The original team of 12 has been subsumed by a larger, more focused organization and I have completely revamped the way we do business. We are ensuring we have the investigators and analysts necessary to fully review currently known exposures, and I have the authority to search out and pursue reports of any new incidents.

My expanded efforts built on earlier work by refocusing and substantially increasing the level of commitment. Much of that increase is to examine incidents which occurred during the Gulf War, the hazardous exposure that may have resulted from these incidents, and the broader implications of such incidents. Working with VA, we are doing this by communicating with veterans concerned in these incidents in 1991, including those veterans who are on active duty, who serve in the Reserve or National Guard, and those who have returned to full-time civilian life.

I have expanded into new areas to initiate a pro-active, risk communication strategy with the two-way communications between DOD, the VA and the Gulf War veterans as recommended by the Presidential Advisory

Committee on Gulf War Veteran's Illnesses (PAC). Today, when a veteran calls our telephone hotline to offer information, the veteran receives a follow-up call and is interviewed by a trained investigator who ensures that information is incorporated into our case files. We are making significant strides in eliminating our backlog in all types of correspondence and in callbacks to our veterans. These calls not only provide an in-depth debrief, but for the future, establish a dialog between a single point of contact in my office and the reporting Gulf War veteran.

The process involves the veteran in the investigative process in a significant and meaningful way. Their information becomes an essential part of the case management process. It is recorded and forwarded to an investigator for analysis, which becomes part of a larger picture as we examine the many incidents and theories associated with Gulf War illnesses. It also serves as a springboard for veteran outreach. The responses from the veterans have been extremely positive.

We are also placing email capability on our GulfLINK website which will enable us to be even more responsive to the concerns of our veterans and to more easily involve them in the investigative process. All of these actions contribute to increasing our understanding.

We also collaborate very closely with veterans service organizations (VSO) to increase their knowledge about potential exposure during the Gulf War. For example, on December 11, 1996 we hosted the VSOs at a demonstration of the protective gear and chemical equipment used during the Gulf War, particularly the M8 alarm, 256 test kits and the FOX chemical reconnaissance vehicle. They appreciated the opportunity to become more familiar with the equipment that has often been described in the media and was the subject of Congressional Debate. Additionally, on January 30, 1997, we hosted a briefing

and tour for VSOs of our new office complex and call back operation which allowed them the opportunity to see how our organization is functioning.

We have also formalized the structure for our incident investigations. We are now preparing a series of narratives that summarize what we know about such incidents as Khamisiyah, the Marine breaching operation, operational logs, Fox alarms, pyridostigmine bromide (PB) tablets and every other issue under investigation. These narratives will be a status report to the American people of what we know, when we knew it, and what actions we plan to take. As we prepare these narratives, they not only show us what we know, but they also, and perhaps more importantly, reveal what we don't know, allowing us to focus our investigative efforts. The first case narrative will cover the events at Khamisiyah and it will be available in the near future. I expect this process will facilitate addressal of the concerns of Gulf War veterans and their families.

The expansion of my office has also allowed us to broaden our focus on possible causes of Gulf War illnesses. For example, we are beginning to devote more resources to the investigation of possible environmental causes such as, pesticides and insecticides. As we reconstruct the events that occurred during the Gulf War, we will look closely at our doctrine, policies and procedures. Was our doctrine adequate? Were our policies and procedures correct? If our doctrine, policies and procedures were correct, then did we follow them? If incorrect, what changes need to be made? We must be completely open minded in our analysis and make the requisite changes based on these lessons learned.

We are building on the major health program initiated by the Department of Defense to care for those still on active duty or otherwise eligible for DOD care. A Comprehensive Clinical Evaluation Program (CCEP) was established to

provide in-depth evaluations of health concerns of Gulf War veterans who are on active duty or serve in the Reserve or National Guard. We have asked all personnel who want to be evaluated to contact the program to schedule an appointment for a medical evaluation. To date, more than 38,000 Gulf War veterans are registered and of those, 30,000 veterans have requested a medical examination. Also, as reported by Dr. Kizer, The Department of Veterans Affairs has completed exams for 63,000-plus veterans. We will coordinate our efforts with VA as appropriate.

As you may know, last month, I withdrew the DOD staff paper published on the GulfLINK home page which discounts low-level exposure as the cause for Gulf War illnesses. In doing this, I noted that the PAC concluded, and current scientific evidence does not support, a causal link between low-level chemical exposures and undiagnosed Gulf War illnesses. However, the PAC also recommended that additional research is warranted. We concur in this assessment and plan to fund the appropriate research. I approach this subject with a completely open mind. Our research agenda is clear evidence of this. Again, we will coordinate this research program with HHS and VA through the established Persian Gulf Veterans Advisory Board

In addition to forming my organization, the Deputy Secretary of Defense generated a number of other important initiatives. In the area of research, the DOD has committed to spend \$12M to study a wide range of medical issues related to the Gulf War. Further, the DOD is prepared to spend another \$15M to study the long-term effects of chemical and other hazardous exposures, including low-level chemical exposure.

Dr. White also initiated a review by the Institute of Medicine of the DOD clinical health examination protocols in light of the possibility of chemical

exposure; a review by the Army Inspector General of military operations at Khamisiyah; and a review by the Assistant to the Secretary of Defense for Intelligence Oversight of the circumstances surrounding the handling of intelligence data concerning Khamisiyah and similar facilities.

Further, Dr. White requested that the National Academy of Sciences provide a mechanism for oversight to meet the President's call for an independent, open, and comprehensive examination of health-related issues and assessment of the multiple issues related to the protection of our forces. The National Academy has deferred now that the PAC has been extended and the PAC is providing oversight of the investigation into low-level chemical exposure events and monitoring of government-wide implementation of its recommendations.

As our investigation and analysis expands and continues, we expect to find new and more complete information. As new information becomes available, it will be provided to you in Congress, to the Presidential Advisory Committee and the American public. You have my assurance that we will continue to disclose fully everything we find, everything we are doing, everything we learn. Our findings will be published on our Internet web site, GulfLINK for public scrutiny. We welcome this oversight.

In conclusion, we are whole-heartedly committed to finding out everything we can about any factor impacting Gulf War illnesses. This is absolutely necessary, not only because it is right for our veterans, but also because it is imperative for the future safety of our troops. The results of our collective effort will be a better understanding of the illnesses facing our Gulf War veterans, a better way of caring for our troops and their families, and new strategies for protecting our troops in the future. Thank you.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

TESTIMONY OF

RICHARD J. JACKSON, M.D., M.P.H.

NATIONAL CENTER FOR ENVIRONMENTAL HEALTH

CENTERS FOR DISEASE CONTROL AND PREVENTION

PUBLIC HEALTH SERVICE

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS

U.S. HOUSE OF REPRESENTATIVES

FEBRUARY 11, 1997

I am Dr. Richard Jackson, Director of the National Center for Environmental Health at the Centers for Disease Control and Prevention (CDC). I am accompanied by Dr. Stuart Nightingale, Associate Commissioner for Health Affairs, Food and Drug Administration (FDA). I am pleased to have this opportunity to appear before the House Committee on Veterans' Affairs to comment, on behalf of the Department of Health and Human Services (HHS), on the final report of the Presidential Advisory Committee on Gulf War Veterans' Illnesses. I will also update you on CDC's activities relating to Persian Gulf War veterans. Dr. Nightingale will be happy to answer questions relating to FDA.

We commend the Presidential Advisory Committee (PAC) for its comprehensive review of the complex issues involved in examining the health consequences of military service in the Persian Gulf War. We take note of the PAC's finding that many veterans are clearly experiencing medical difficulties connected with their service in the Gulf War. In fact, our own studies have reached a similar conclusion. The causes of these illnesses need to be thoroughly investigated. However, answering such questions is exceedingly complex and we may never be able to determine the precise causation of illness in all Persian Gulf War veterans. That is why it is important that we also examine future actions that can be taken to control or prevent health problems among our military personnel. In this regard it is essential that HHS continue its close collaboration with the Departments of Defense (DoD) and Veterans Affairs (VA). This collaboration has resulted in several well-designed investigations of health outcomes among Persian Gulf War veterans. Later in this testimony, I will describe two of these investigations, one based in Iowa and the other in Pennsylvania. However, there have been several other collaborations, including studies of birth defects among children born to Persian Gulf War veterans, testing of serum samples for leishmania infection, and assessment of the impact of the oil well fires.

We concur with the PAC on the importance of communicating risk and providing health education to Gulf War veterans. Several centers at CDC, including the National Institute for Occupational Safety and Health, and CDC's sister agency, the Agency for Toxic Substances and Disease Registry, have extensive expertise in this area will collaborate with DoD and VA in developing effective methods to provide Persian Gulf War veterans with comprehensive information concerning possible exposures to environmental hazards, potential health effects from risk factors, and explanations of ongoing and completed clinical and epidemiologic studies.

The PAC strongly emphasized the important role of public advisory groups. HHS strongly supports the concept of community involvement and participation in our studies and programs. At CDC we have found that such participation increases public awareness of the strengths and limitations of epidemiologic studies of public health issues and enhances public acceptance of study results. Such groups provide useful information and advice, frequently even on complex public health and scientific issues.

Our use of a public advisory group in the Iowa study of Persian Gulf War veterans is an excellent example of the effectiveness of community involvement. In this study, the Iowa Department of Public Health established a public advisory committee to ensure coordination, liaison, and open communication with veterans, veterans' service organizations, and other affected parties regarding the Iowa study. In its review of the study protocol and data collection instruments, the public advisory committee provided very useful input regarding question format and content. The public advisory committee was also essential in disseminating information regarding the study to veterans groups. The committee increased veterans' awareness of the study and

encouraged their participation by printing information regarding the study in veterans' newsletters. We achieved a very high rate of participation in this study, in part due to the public advisory committee's support of the study.

As pointed out in the PAC report, appropriate peer review is also essential to the success of scientific endeavors. In the Iowa study, investigators at the University of Iowa College of Medicine established a scientific advisory committee to provide external scientific review of study methods and survey instruments. The six-member committee was composed of nationally recognized experts in epidemiology, biostatistics, environmental health, psychiatry, infectious diseases, multi-systemic conditions, respiratory disease, and reproductive health. They provided critical review of our study at several stages of development and played an important role in ensuring the scientific validity of the study.

The PAC identified several priority research areas. These include studies of the long-term health effects from low-level exposure to chemical agents, the long-term health effects from stress, the long-term health effects from exposure to known carcinogenic and mutagenic compounds, such as mustard agent, and the long-term health effects of interactions between pyridostigmine bromide and other chemicals. We concur with the importance of conducting additional studies in these areas.

HHS is also in full agreement with the PAC on the importance of anticipating post-conflict health concerns associated with military deployment. The ongoing studies of Persian Gulf War veterans will contribute to our understanding of the effects of military service in the Persian Gulf. However, most of these studies are limited by their retrospective nature. At CDC, we are well aware of the difficulties associated with attempting to address veterans' health concerns which develop months or

sometimes years after deployment. In most instances, investigators are called in only after an environmental health problem is suspected. As a result, baseline data on the health of military personnel is often lacking, and this limits the ability to conduct definitive studies. It is essential that we take a more forward-looking approach to evaluating veterans' health concerns. Such an approach should consist of gathering baseline data on the health of military personnel, establishing surveillance systems for adverse health outcomes, developing better troop locator methods, and identifying risk factors for stress-related reactions. Ideally this would include collection and storage of baseline and post-deployment serum samples.

In particular, in the study of low-level chemical exposures, the use of pre- and post-deployment serum samples coupled with an investment in laboratory-epidemiology partnerships may develop objective measures of exposure. Laboratory measures of exposures can be much more relevant and predictive than surrogate estimates from self-reported information obtained many years after the exposure. CDC has had a number of successes in the development of methods to measure exposure to environmental toxicants in humans. For example, CDC laboratories developed new techniques for measuring volatile organic compounds and used these techniques to measure exposure to oil well fire smoke in Kuwait.

We also commend the PAC for their emphasis on the study of stress-related disorders. As the report points out, stress is known to affect the brain, immune system, cardiovascular system, and various hormonal responses. Further study of the impact of stress on physical as well as psychologic functioning can only benefit our efforts to understand the illnesses affecting Persian Gulf War veterans and assist us in preventing similar illnesses in future deployments.

The PAC report recommends that the government consider methods for routinely sampling military populations regarding reproductive health so that an appropriate baseline exists for evaluating reproductive outcomes following deployment. In particular, the report suggests that DOD consult with the CDC's National Center for Health Statistics and consider implementing the National Survey of Family Growth. This is a survey of women of child bearing age that provides baseline and evaluation data for a variety of health promotion programs concerned with reproductive health, family planning, maternal and child health, sexually transmitted diseases, and HIV infection. CDC would be pleased to provide technical consultation to DoD on developing such a surveillance system.

Finally, the PAC report commented on FDA's Interim Final Rule permitting waiver of informed consent for use of unapproved products in a military emergency. The committee expressed concern about the time FDA has taken to reopen the rule making process. The FDA intends to reopen the rule making process and solicit public comment in line with the committee's report. This public comment will be directed toward whether the FDA should finalize the Interim Final Rule, modify it, or eliminate it completely. We also will continue to work -- as we have over the past several years -- with the DOD and others on this important topic.

In addition to the findings from the PAC, the Institute of Medicine (IOM) also recently released a report on its findings regarding the health consequences of service during the Persian Gulf War. I will not specifically address the recommendations made in the IOM report as there is considerable overlap with the findings and recommendations of the PAC report.

I would like to update you on CDC's recent activities relating to Persian Gulf War veterans. In April 1994, Senator Harkin

requested that CDC conduct a health assessment of Persian Gulf War veterans from Iowa. The study was initiated in December 1994 and was conducted in collaboration with the Iowa Department of Public Health and the University of Iowa College of Medicine. The purpose of this study was to compare the prevalence of self-reported symptoms and illnesses among Persian Gulf war veterans from Iowa with military personnel from Iowa who were not deployed to the Persian Gulf. Initial results from this study appear in the January 15th issue of the *Journal of the American Medical Association*.

Of all Gulf War studies, the Iowa-CDC study has unique strengths and differs from previous reports on the health of Gulf War veterans in several substantial ways. First, the individuals in the Iowa study are not self-identified. This study is the first population-based epidemiological study to evaluate the health consequences of the Persian Gulf War. The 3,695 subjects in the study were selected from a larger population of almost 29,000 military personnel who listed Iowa as their home of record. Furthermore, the subjects in this study were specifically selected to represent individuals from all four DOD branches of the military, and include both regular military personnel and National Guard and reservists. The interviews for the study were conducted by telephone. This resulted in a high rate of participation. In fact, 91% of persons contacted by telephone completed the detailed interviews.

Secondly, this study is one of the first "controlled" epidemiological studies to evaluate the health consequences of the Persian Gulf War. By controlled, I mean it also assessed a carefully selected comparison group of military personnel who were not deployed to the Persian Gulf but who served during the time of the Persian Gulf War.

Finally, this was a rigorously conducted study with a great deal of scientific review and oversight. As previously described, we relied on input from our scientific and public advisory committees throughout the course of the study.

The study's researchers found that Gulf War military personnel in this study were more likely than those who did not serve in the Gulf War to report symptoms suggestive of cognitive dysfunction; depression; chronic fatigue; post-traumatic stress disorder; and respiratory illness, specifically asthma and bronchitis. The conditions identified in this study appear to have had a measurable impact on the functional activity and daily lives of these Persian Gulf War veterans. Among Persian Gulf War veterans, minimal differences were observed between the National Guard or Reserve troops and the regular military personnel, indicating that all military personnel, regardless of type of military service, were affected by deployment to the Persian Gulf.

Findings from this study establish the need to investigate further the causes, clinical nature, and public health implications of the higher rates of self-reported health problems of Gulf War veterans. More objective clinical measurement of the specific conditions identified in this study should be addressed in future studies to determine the underlying illnesses, medical conditions, or other concerns that might be related to these self-reported conditions.

In addition to the Iowa study, CDC also conducted an epidemiologic investigation of illness among members of an Air National Guard unit in Pennsylvania. In October 1994, a physician from the Lebanon (Pennsylvania) VA Medical Center reported a cluster of patients with multiple symptoms including diarrhea, joint pains, and skin lesions in an Air National Guard unit that had served in the Persian Gulf. In November 1994, the

Pennsylvania State Health Department, VA, and DoD requested that CDC conduct an independent evaluation of these veterans.

The investigation involved three phases. In Phase 1, the veterans were interviewed, examined, and their medical records reviewed to verify and characterize the illness. In Phase 2, a survey was conducted with members of the index unit and three control units to determine the relative prevalence of symptoms among persons deployed to the Persian Gulf compared with those who were not deployed. This was done in order to develop a working case definition. In Phase 3, a comprehensive clinical evaluation of Persian Gulf War veterans from the index unit was completed to characterize the illness and identify risk factors.

The findings from the first two phases of this investigation have been reported in June 1995 in CDC's publication, the *Morbidity and Mortality Weekly Report*. This investigation demonstrated an association between deployment to the Persian Gulf and a chronic multi-symptomatic condition characterized by fatigue, mood and cognitive symptoms, and musculoskeletal pain. These are similar symptoms to those reported in the Iowa study. In the Pennsylvania study, 45 % of veterans and 15% of non-veterans met the case definition of illness. Case subjects reported significant decreases in functioning and well-being, but illness was not associated with abnormalities on physical exam or laboratory analyses or with exposure to infectious agents. CDC is preparing a report on these findings for publication in a peer-reviewed journal.

In summary, although DoD and VA have the primary responsibility for protecting the health of military personnel, HHS strongly supports the findings of the PAC that all of the government's expertise be brought to bear on this issue. HHS has played an appropriate role in addressing Persian Gulf War veterans' health concerns through our membership and participation in the

activities of the Persian Gulf Veterans' Coordinating Board. To the extent possible, HHS is committed to continue working closely with VA and DoD in this effort. We owe a debt of gratitude to these veterans and to all men and women who volunteer for military service and we are strongly committed to improving the quality of their health. I will be glad to respond to any questions you or other members of the Committee may have.

MATTHEW L. PUGLISI
ASSISTANT DIRECTOR FOR GULF WAR VETERANS
VETERANS AFFAIRS AND REHABILITATION COMMISSION
THE AMERICAN LEGION

BEFORE THE

HOUSE VETERANS' AFFAIRS COMMITTEE
U.S. HOUSE OF REPRESENTATIVES

FEBRUARY 11, 1997

Mr. Chairman and distinguished members of the Committee:

The American Legion appreciates the opportunity to offer testimony concerning the *Final Report* of the Presidential Advisory Committee on Gulf War Veterans' Illnesses (PAC). We commend you, Mr. Chairman, for convening this hearing on a document that has, and will continue to have, a significant impact on how the federal government responds to Gulf War illnesses (GWI).

The PAC's *Final Report* is an important contribution to the GWI literature. The American Legion commends the Committee and staff on its professionalism, hard work, and dedication to a complex and emotional topic. The American Legion attended every Committee and Panel meeting over these many months, and we were impressed with the presenters, the PAC's attention to detail, and the opportunities for extensive periods of public comment.

On balance, the *Final Report* is a thoughtful analysis of the federal government's response to, and the nature of, GWI. The compilation of clinical and epidemiological data is the most complete and well organized on this topic. The PAC, and its *Final Report*, has had a significant positive impact on some areas of the federal government's response to GWI, notably the Department of Defense's (DoD) investigation into chemical and biological weapons (CBW) exposures. The *Final Report* has a number of weaknesses, however, most notably its inability to adequately evaluate the medical treatment provided to Gulf War veterans from DoD or the Department of Veterans Affairs (VA), and its chapter describing the likely role of stress in the illnesses.

Background

Soon after the Gulf War, reports surfaced that Persian Gulf veterans were suffering from poor health. It soon became clear to The American Legion that many of its members who were Gulf War veterans and who deployed to the Persian Gulf in good health, returned in poor health. For many, the myriad of symptoms that have come to be known as "Gulf War Syndrome" became manifest after their return from the Persian Gulf. The American Legion thinks that these symptoms are most likely more accurately described as Gulf War Illnesses (GWI). GWI includes symptoms that go without a diagnosis during a medical examination, particularly Persian Gulf protocol exams offered by DoD and VA. The federal government responded slowly at first, and with minimal coordination between the three primary agencies tasked with addressing GWI: DoD, VA, and the Department of Health and Human Services (HHS). The American Legion was dismayed at the federal government's poor overall initial response, and soon a number of Congressional oversight hearings occurred. As VA's programs improved, and formal coordination between the agencies was established, certain controversies only grew, particularly the connection between illnesses and exposure to CBW agents in the Persian Gulf.

President Clinton created the PAC on May 26, 1995 at the request of the First Lady. She developed the idea for independent oversight after meetings with federal agencies, VSOs and Gulf War veterans. The PAC was charged with reviewing the federal government's response to Gulf War veterans' illnesses and with providing advice and recommendations on the following matters:

- Research
- Coordinating Efforts
- Medical Treatment
- Outreach
- External Reviews
- Risk Factors
- Chemical and Biological Weapons¹

The PAC conducted ten full committee meetings and eight panel meetings throughout the country during its initial tenure.² The PAC was extended nine months by the President on January 7, 1997. The President did so for two reasons: the PAC can satisfy its own recommendation that a group independent of DoD oversee the investigation into CBW exposures; the PAC can oversee the implementation of its recommendations by the federal government.

Mr. Chairman, I would now like to offer The American Legion's analysis of the *Final Report's* strengths and weaknesses.

Strengths

Chemical and Biological Warfare Agent Exposures and DoD's Investigation

The PAC will long be remembered for the impact it had on DoD's investigation of possible CBW exposures of U.S. troops in the Persian Gulf. This impact cannot be overstated. DoD maintained for over five years after the Gulf War that there was no presence, no use and no exposure of U.S. troops to chemical warfare agents in the Kuwaiti Theater of Operations; the "three 'nos'" as now famously described by the PAC.³ DoD no longer maintains that position, and it now has over ten times the manpower devoted to this investigation. The new point man for the issue at DoD, Dr. Bernard Rostker, Assistant Secretary of the Navy for Manpower and Reserve Affairs, in recent Congressional testimony described DoD's investigation prior to his appointment in November 1996 as "inadequate."⁴ His testimony signaled how completely DoD has changed its tune.

DoD has described its June 21, 1996 Khamisiyah announcement as a "watershed event." The announcement revealed that U.S. troops had demolished an Iraqi ammunition bunker in March 1991 that contained chemical munitions. This announcement followed years of the aforementioned "three nos." DoD has claimed that the June 21 announcement and subsequent turnaround occurred because of the investigative work of the Persian Gulf Veterans' Illnesses Investigation Team (PGIT). PGIT was a twelve member operation created in 1994 that reported to the Assistant Secretary of Defense for Health Affairs, Dr. Stephen Joseph. PGIT no longer exists, and its members no longer work on the investigation of CBW exposures for DoD. If its work led the largest government agency known for its inability to admit mistakes to execute a complete policy turnaround, PGIT's members would be wearing Defense Superior Service Medals today, instead of being dropped from the investigation altogether. The truth of the matter is that PGIT's poor performance was revealed by the PAC's investigation, and the PAC's articulate and damning judgment of the PGIT doomed it to extinction. The watershed event occurred on *Sept. 5, 1996*, and the group behind DoD's about face was not the PGIT but the PAC.

The PAC's staff reported their findings and recommendations concerning their investigation into DoD's efforts on September 5, 1996 in Washington, DC. Their professional report was a display of government oversight at its best. In plain language understandable to the layman the staff left no doubt that, in its words, "PGIT's analyses related to CBW incidents have lacked vigor, fallen short on investigative grounds, and stretched credibility."⁵ The staff's report made headlines, and the language it used to describe its findings found its way onto editorial pages of most of the nation's newspapers. The report articulated what veterans themselves thought about DoD's efforts, but did so in a much more powerful manner. DoD had no choice but to quickly review and renew its efforts, or watch as the momentum generated by the PAC forced it out of the game entirely.

Deputy Secretary of Defense Dr. John White ordered Dr. Rostker to conduct a complete review of DoD's efforts 20 days after that staff report. Dr. Rostker reported back to Dr. White in November 1996 on his findings and recommendations. Dr. White announced his plan for revamping DoD's entire effort concerning Gulf War veterans' illnesses, and the investigation of CBW exposures, at the November 13, 1996 PAC meeting in Washington, DC.

The PAC's aggressive and thorough investigation, and the articulate and damning staff report sparked the Pentagon to revamp its entire approach to GWI months *before* the *Final Report* was submitted to the President. The American Legion, grassroots groups, some regional news outlets and a few Congressional Committees kept pressure on the Pentagon concerning CBW exposures for several years after the Gulf War. It was the PAC, however, that pushed the Pentagon to conduct a complete about face.

Avoiding Post-Conflict Health Concerns

The Committee noted the parallels between the experience of Vietnam and Gulf War veterans, and recommended how the federal government could avoid, or at least ameliorate, post-conflict health concerns.⁶ The Committee was not charged with comparing the two, but it wisely did so.

War and subsequent disease in war veterans has been noted and observed since the U.S. Civil War,⁷ with often baffling and overlapping results. There are four general categories of disease that have occurred in war veterans, and none of them are necessarily mutually exclusive.

The first includes common diseases spread in epidemic settings such as overcrowded and unsanitary trenches in World War I, to overcrowded and unsanitary barracks during the Gulf War. Tuberculosis was a well known result from the First World War, and several respiratory diseases were reported after the Gulf War. It is significant to note that World War I veterans who suffered from TB were initially labeled as malingerers by the War Department.

The second includes diseases whose causes were poorly understood when first encountered or which are rarely seen by American medical doctors. Examples include lung cancer in World War I veterans exposed to mustard gas, diseases caused by exposure to dioxin in Vietnam veterans, and Leishmaniasis in some Gulf War veterans.

The third category includes psychological illnesses caused by exposure to combat, the chief and most disabling among them being Post-traumatic Stress Disorder (PTSD).

To these we must add so called "war syndromes." (Hyams) They have been observed and described since the U.S. Civil War. They include reported symptoms that are not verifiable through diagnostic tests, and the most frequently reported symptom is fatigue. It is not yet known if Gulf War Syndrome, or GWI, are to be included in these syndromes. GWI include credible reports of poor health in some family members of Gulf War veterans, and reports of adverse birth outcomes among Gulf War veterans and spouses and birth defects among children of Gulf War veterans. Gulf War veterans also encountered environmental hazards in the Persian Gulf that were not present in past wars, such as pyridostigmine bromide (PB) and sarin.

The disabilities that sick veterans have faced after these conflicts have sometimes been exacerbated by the federal government's response, or lack of response to them. The PAC's recommendations, if implemented, should help avoid these problems in the future to a certain extent. Its recommendations are:

- The government should plan its response for future post-conflict periods today
- VA, DOD and FDA should develop a comprehensive risk communication strategy
- Data collection should be improved and made more uniform

All address the historical mistakes, and the federal government's lack of vision on many issues affecting veterans' health, from World War I to the Gulf War.

The American Legion would like to add recommendations that, if implemented, would provide the federal government with a comprehensive approach to post-conflict health and adjustment problems for veterans and their *families*. The GI Bill of Health, and much needed improvements in the current Montgomery GI Bill would provide future veterans with access to quality health care and effective transition assistance. Mr. Chairman, The American Legion encourages you, and this Committee to consider these proposals in light of the Gulf War veterans' experience. That experience clearly demonstrates that health care and transition assistance would have made the plight of sick Gulf War veterans less severe.

Recommendations

The PAC's many recommendations must all be implemented in good faith and as quickly as possible. As a group, they address the major and minor shortfalls of the government's response to GWI. Some recommendations from the PAC's *Interim Report* have not been implemented, notably the use of public advisory committees for research projects, and CBW detection equipment improvements. The extension of the PAC's charter should enable it to oversee the implementation of its recommendations, but this Committee is encouraged to play an active oversight role in conjunction with the PAC.

Weaknesses

Evaluation of Risk Factors

The PAC identified ten risk factors encountered by troops in the Persian Gulf and it considered their likely association to GWI based on current peer reviewed research. The risk factors considered were:

- chemical warfare agents
- biological warfare agents
- stress
- pyridostigmine bromide
- smoke from oil well fires
- vaccines
- indigenous infectious disease
- depleted uranium
- pesticides
- petroleum products⁸

Sick Gulf War veterans were stationed all over the theater of operations. Some were exposed to all or few of the risk factors, and yet all report poor health. It is unjustified to favor one risk factor above any of the others until the scientific studies are completed. Some appear more likely than the others, especially for veterans who experienced particular exposures. Judgment and speculation are best reserved at the end of the investigative process, not the beginning. This, however, was not the approach of the PAC.

The PAC did not find a causal link between any of the aforementioned risk factors and GWI, except stress.⁹ The *Final Report* describes in detail the well defined, and well known psychological consequence of exposure to traumatic stress--PTSD--and the subsequent poor *physiological* health found in PTSD patients. However, except for the Southwick¹⁰ and Stretch¹¹ studies, PTSD does not appear as a major contributor to symptoms associated with GWI. This has been found by a number of epidemiological studies conducted by the Centers for Disease Control,¹² the Boston VA Environmental Hazards Center,¹³ the Iowa Persian Gulf Study Group,¹⁴ and the University of Texas.¹⁵ All of these studies, except the Texas study, carefully screened for PTSD, and found PTSD in some veterans. All however, found a group of veterans suffering from symptoms of fatigue, joint and muscle pain, headaches, etc., but who did not meet the criteria for PTSD. This group's symptoms also went undiagnosed. PTSD does not explain GWI, because those

whose symptoms fall into its (very broad) category do not suffer from PTSD according to most of the peer reviewed research findings reported to date.

The *Final Report* alludes to ongoing research that is investigating the link between *non-traumatic stress* and adverse physiological health outcomes. This research is fascinating, and in its early stages. The *Final Report* recognizes this fact by carefully explaining that “scientists are *beginning to unravel* the physiological connection between the brain and various parts of the human body,” and, furthermore, that “some researchers *suspect* that the inadequate production of stress hormones and stress response occurs in some (not all) humans with CFS [Chronic Fatigue Syndrome] and PTSD.”¹⁶ [Emphasis added] Suspicions are not data or research findings, and the PAC’s finding that stress is a likely cause of GWI is premature at best. One of the nation’s leading PTSD experts recently commented that “‘likely’ should not be used by the PAC to describe stress. Not yet.”¹⁷

The principles of risk communication were not applied by the PAC in writing this chapter of its final report. To the lay reader, the PAC seems to contradict itself by dismissing nine risk factors (including PB and CBW) while it calls for more research into PB and low level CW exposures. The PAC’s finding concerning stress as a likely risk factor without data has alarmed veterans, and disappointed some researchers. This most important of chapters should have been written with the target audience, Gulf War veterans, more in mind.

The PAC would do well to follow its own advice to VA, DoD and FDA concerning risk communication. Chapter Four of the *Final Report* has generated a great many questions by veterans, and the PAC should make an effort to thoughtfully and effectively address them during the remainder of its extended tenure.

Medical Treatment Provided to Gulf War Veterans

The PAC charter called for it to report to the President on the medical treatment offered to Gulf War veterans at VA and DoD.¹⁸ It found that overall, Gulf War veterans are provided with “high-quality health care.”¹⁹ The PAC’s finding was not based on data collected from a formal outcomes study, but from several site visits and public comment at its meetings. Its methods and the lack of data do not support such a definitive finding.

How do Gulf War veterans *feel* after they receive treatment from VA and DoD? Do they feel better? The same? Worse? As of today, no one knows. There is no data available, only anecdotes. VA and DoD have not formally measured health outcomes for Gulf War veterans after they receive care from those agencies. The PAC did not conduct outcomes studies because it was not permitted under its charter to conduct original research. It should have noted this limitation, however, instead of weakening its *Final Report* with such a definitive finding.

After hearing many veterans complain about the care they received from VA and DoD during public comment, the PAC did not follow-up by recommending to VA and DoD that they conduct investigations into the quality and effectiveness of the health care they provide to Gulf War veterans.

The American Legion, in discussions with DoD, and as part of its membership on VA’s Persian Gulf Expert Scientific Committee, has recommended to both agencies that they undertake outcomes studies to assess the effectiveness of the medical treatment they provide to Gulf War veterans. Both have responded favorably.

Summary

Overall, the PAC’s *Final Report* accomplished the mission given to the PAC in its charter: evaluate the federal government’s response to Gulf War veterans’ illnesses. In some areas, the PAC had a significant positive impact on the government’s response, particularly DoD’s investigation into CBW exposures. In others, notably medical treatment provided to Gulf War veterans, it fell short of the mark. The American Legion commends the PAC, and its staff, for their professionalism and

dedication to helping Gulf War veterans receive the care and answers that they deserve.

This completes my testimony. I will now be happy to answer any questions that you may have.

¹ Executive Order 12961, May 26, 1995.

² *Presidential Advisory Committee on Gulf War Veterans Illnesses: Final Report* (Washington, DC: U.S. Government Printing Office, December 1996).

³ Turner, J.C., staff report before the PAC, September, 1996.

⁴ Rostker, B., testimony before the Senate Veterans Affairs Committee, January 1997.

⁵ PAC, p. 45

⁶ PAC, p. vii

⁷ Hyams, K.C., Wignall, F.S., and Roswell, R., "War Syndromes and Their Evaluation: From the U.S. Civil War to the Persian Gulf War," *Annals of Internal Medicine* 125(5):398-405, 1996.

⁸ PAC, p. 45

⁹ PAC, p. 125

¹⁰ Southwick, S., Morgan, C.A., Darnell, A., et al., "Trauma-Related Symptoms in Veterans of Operation Desert Storm: A 2-Year Follow-Up," *American Journal of Psychiatry* 152:1150-1155, 1995.

¹¹ Stretch, R.H., Marlowe, D.H., Wright, K.M., et al., "Post-traumatic Stress Disorder Symptoms among Gulf War Veterans," *Military Medicine* 161:407-410, 1996.

¹² Reeves, W., Chief, Division of Viral Exanthems and Herpes Virus Branch, National Center for Infectious Diseases, Centers for Disease Control and Prevention, presentation to the Department of Veterans Affairs Persian Gulf Expert Scientific Committee, November, 1996.

¹³ Friedman, M.J., Executive Director, National Center for Post-traumatic Stress Disorder, presentation to the Department of Veterans Affairs Persian Gulf Expert Scientific Committee, November, 1996.

¹⁴ Schwartz, D.A., et al., "Self-reported Illness and Health Status Among Gulf War Veterans," *The Journal of the American Medical Association* 277:238-244, 1997.

¹⁵ Haley, R.W., et al., "Is There a Gulf War Syndrome?," *The Journal of the American Medical Association* 277:215-222, 1997.

¹⁶ PAC, p. 124

¹⁷ Friedman, M.J., presentation to the Department of Veterans Affairs Persian Gulf Expert Scientific Committee, January, 1997.

¹⁸ PAC, p. 143

¹⁹ PAC, p. 47



★ WASHINGTON OFFICE ★ 1808 "K" STREET, N.W. ★ WASHINGTON, D.C. 20006-2847 ★
(202) 861-2700 ★ FAX (202) 861-2728 ★

February 11, 1997

Honorable Bob Stump, Chairman
House Veterans Affairs Committee
335 Cannon House Office Building
Washington, DC 20515

Dear Mr. Chairman:

Neither I, nor The American Legion, has received any federal grant or contract from any agency or program relevant to The Final Report of the Presidential Advisory Committee on Gulf War Veterans' Illnesses, the subject of the testimony offered today, during the current or previous two fiscal years.

Sincerely,

Matthew L. Puglisi
Assistant Director
Gulf War Veterans

MATTHEW L. PUGLISI

Assistant Director. The American Legion, Washington, DC. October 1, 1995-Present. Responsible for the creation of innovative policies to enhance The American Legion's service towards Persian Gulf War Era veterans, their families, and their advocates. Conducted a systematic review of the ongoing studies concerning undiagnosed illnesses and service in the Persian Gulf. Represented The American Legion on the Department of Veterans Affairs' Persian Gulf Expert Scientific Committee. Studied the VA's claims process as it relates to Gulf War veterans. Conducted outreach to Gulf War veterans, and their advocates, through the traditional media, American Legion publications, and the Internet.

Commanding Officer. Battery G, 3rd Battalion, 14th Marines, United States Marine Corps Reserves, West Trenton, New Jersey. August 1995-Present. Responsible for the training, and performance, of 130 Marines and six officers. Responsible for the accurate and timely fires from the battery's six 155mm towed howitzers.

Appeals Representative. The American Legion, Washington, DC. January 16, 1995-September 30, 1995. Counseled, prepared and represented veterans before the Army, Naval, and Air Force Discharge Review Boards. Presented written arguments on behalf of veterans before the Boards for Correction of Military Records.

Senior Aide. New York State Assemblywoman Eileen C. Dugan, Brooklyn, New York. May 1993-January 1995. Developed position papers and conducted presentations to public and private policy and decision making groups. Testified before legislative committees. Coordinated legislative hearings and briefings for community groups and businesses. Acted as ombudsman to resolve complex problems for constituents.

Artillery Officer. United States Marine Corps. Second Marine Division, Camp Lejeune, North Carolina. September 1989-April 1993. Acted as the Commanding Officer of an artillery battery. Planned, organized and coordinated a formal training program for 130 Marines. Coordinated artillery, mortar and air power for a mechanized infantry company during Operation Desert Storm.

Education. Siena College, Loudonville, New York. BA, cum laude (Political Science), 1989.

**STATEMENT OF
JOSEPH A. VIOLANTE
DEPUTY NATIONAL LEGISLATIVE DIRECTOR
OF THE
DISABLED AMERICAN VETERANS
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES
FEBRUARY 11, 1997**

MISTER CHAIRMAN AND MEMBERS OF THE COMMITTEE:

Since 1920, the Disabled American Veterans (DAV) has been dedicated to one single purpose: building better lives for disabled veterans and their families. On behalf of the more than one million members of DAV and its Auxiliary, I wish to express our deep appreciation for this opportunity to provide the Committee with DAV's assessment of the difficulties faced by Persian Gulf War veterans as they attempt to obtain disability compensation and medical care for their illnesses and disabilities from the Department of Veterans Affairs (VA). We also appreciate the opportunity to provide our comments regarding the recent report by the Presidential Advisory Committee on Gulf War Veterans' Illnesses (PAC Report).

At the outset, Mr. Chairman, we wish to thank you, Ranking Democratic Member Lane Evans, and the members of the Committee for the timely exercise of your oversight responsibilities. We appreciate the fact that you have made Persian Gulf War illnesses one of this Committee's priorities. By focusing your attention on the needs of Persian Gulf War veterans and their families, you have demonstrated, in a most meaningful way, your commitment to ensuring that these veterans and their families receive the VA benefits and services to which they are entitled.

Mr. Chairman, the issue of Persian Gulf War illness is a serious problem made more difficult because of its complexity, the lack of scientific/medical evidence, the failure to maintain complete military and medical records, the failure of the Department of Defense (DoD) to come forward with critical evidence establishing the possible exposure to chemical agents by U.S. troops, and the conflicting reports and conclusions being reached by various scientific/medical commissions and individuals. These are not new dynamics for veterans. Veterans returning from all our Nation's military wars and conflicts have been faced with similar problems in attempting to establish the foundation for recognizing the onset of certain conditions as service-connected; however, Persian Gulf War veterans, as a group, appear to be sicker and more severely disabled as a result of their service in the Persian Gulf than their predecessors. The fact that there are still many unanswered questions and so many conflicting medical opinions surrounding Persian Gulf illness only serves to exacerbate the situation.

When it became evident in early 1994 that a large number of Persian Gulf War veterans were becoming ill for no apparent reason other than the fact of their service in the Persian Gulf, DAV wrote to Secretary of Veterans Affairs Jesse Brown to express our significant concerns about the plight of these men and women. We called upon the Secretary to provide just compensation to veterans suffering illness or disease believed to be associated with their service in the Persian Gulf. We also urged the VA to continue its vigorous pursuit to identify the cause(s) of these ailments and their possible treatment and cure.

When it became obvious that legislation would be required to provide VA disability compensation to Persian Gulf War veterans suffering from undiagnosed illnesses, DAV wholeheartedly supported that initial legislation with the exception of two provisions. We took exception to the one-year presumptive period originally proposed in the legislation. At that time, we warned Congress and VA that with the difficulty in pinpointing the source or sources of the various ailments, the one-year presumptive period was inadequate for the purpose of compensating veterans who were suffering from illness or disease attributed to their service in the Persian Gulf. We noted that primary investigations and multifarious studies have attempted to identify the source or sources of these ailments without success. We suggested that the

presumptive period be left open-ended until the scientific/medical community could determine the cause or causes of these ailments. A two-year period was established by VA, however. We believe that the passage of time has demonstrated the soundness of our position.

Mr. Chairman, we continue to espouse the position that the presumptive period be left open-ended until the cause(s) of these ailments can be determined. It did not make sense in 1994 to limit the presumptive period and it does not make sense today since we still know very little about the ailments afflicting Persian Gulf veterans.

We note that Congress wisely provided the Secretary with the discretion to establish the presumptive period, and that Secretary Brown is currently in the process of expanding the presumptive period from its current two-year period. We urge this Committee to encourage the Secretary to establish an open-ended presumptive period, until such time that we know more about the cause or causes of these mysterious ailments. We caution this Committee, however, not to take legislative action that would trigger "pay-go" provisions of the Budget Enforcement Act.

As you know, when Congress enacted Public Law 103-446, the "Veterans' Benefits Improvement Act of 1994," cost-of-living adjustments for service-connected disabled veterans and survivors were reduced to satisfy the "pay-go" provisions of the Budget Enforcement Act. Should Congress legislate a change in the presumptive period for Persian Gulf illness, it would have adverse repercussions on other VA programs because VA, once again, would have to identify cost savings from other programs to pay for this "new" benefit.

It appalls us to think that in order to establish new veterans' benefits or programs, some other worthy program must be cut or wartime disabled veterans or their dependents would have to give up their compensation to fund these new benefits or programs. Our Nation must realize that paying for the disabilities of wartime disabled veterans is nothing more than an extension of the cost of war waged by our Government. It is unconscionable to think that one group of wartime disabled veterans must give up an entitlement so that another worthy group of wartime disabled veterans can receive benefits or services to which they are entitled. We call upon this Committee and all members of Congress to exempt veterans' benefits and services from the "pay-go" provisions of the Budget Enforcement Act.

Mr. Chairman, the plight of Persian Gulf War veterans suffering from undiagnosed illnesses continues to be one of our foremost concerns, as we know it is with this Committee. Recent VA statistics on claims processing for these veterans only serves to heighten our concerns. The VA notes that slightly more than three-quarters of Persian Gulf veteran claims have been allowed. Of the 84,147 Persian Gulf claims, service connection has been granted in approximately 65,001 claims; however, only slightly more than 27,000 veterans are receiving compensation for service-connected disabilities. Further, of the 11,257 environmental hazard claims considered, slightly less than 1,400 have been granted service connection and only 620 or 5% have been granted service connection for undiagnosed illnesses.

Although the VA is proud of its 77% allowance rate, we are concerned that many veterans do not receive service connection for their most debilitating ailments. For example, a veteran files a claim for so-called Persian Gulf illness with symptoms such as joint pain, fatigue, a respiratory condition, memory loss, headaches, and gastrointestinal problems, and for an in-service back injury. Service connection is granted at a non-compensable rate for the in-service back injury residuals and denied for the other disabilities. Statistically, this veteran would fall into the category of claims allowed (77%); yet, his or her most debilitating disabilities are nonservice-connected. We have asked the VA to look at those claims allowed to determine what disabilities have been denied.

To the VA's credit, they have reviewed, or are in the process of reviewing, 11,000 claims where service connection was denied. Slightly more than 2,000 (19%) of those claims have been readjudicated and service connection has been granted in approximately 250 of those previously denied cases.

Mr. Chairman, in addition to not receiving adequate compensation for their illnesses, Persian Gulf veterans face a two-prong dilemma. Although most experts concede that these veterans were exposed to a wide range of environmental hazards, such as experimental drugs, high levels of toxic substances from the oil field fires, radioactive residue, parasites, pesticides, lead paint, and chemical agents, there is little consensus in the medical/scientific community as to the residuals, if any, from these exposures. Due to the confusion surrounding Persian Gulf illness, we question whether these veterans are receiving adequate medical care from VA and DoD for their illnesses.

The most frustrating aspect of Persian Gulf illness is that, six years after the end of the Persian Gulf War, we are still unable to answer the question about what is causing these undiagnosed illnesses. Unfortunately, the PAC report does not provide any concrete answers to the question of what is causing Persian Gulf illness. While the PAC has stated that “veterans clearly have service-connected illnesses,” they conclude that the current scientific evidence does not demonstrate a causal connection between so-called Persian Gulf illnesses and the environmental risk factors that veterans were exposed to in the Persian Gulf. These environmental risk factors include: pesticides, chemical and biological warfare agents, vaccines, pyridostigmine bromide, infectious diseases, depleted uranium, oil well fires and smoke, and petroleum products.

The Committee does note, however, that further investigation is required to determine the long-term effects of exposure to low-level chemical warfare agents and the synergistic effects of exposure to pyridostigmine bromide and other risk factors. The Committee also cautioned that some of the environmental risk factors were potential carcinogens and that there was a possibility of an increase in the risk for cancers after decades following the end of the war. It is our sincere hope that DoD and VA will continue to track these veterans and monitor them for any increased cancer risks.

The PAC report focuses on stress as a likely contributing factor to the broad range of physiological and psychological illnesses currently being reported by Persian Gulf veterans. It is noted that currently, scientists are beginning to “unravel the psychological connection between the brain and various other parts of the human body” (p. 124). Additionally, it was noted that, based on decades of clinical observations, physicians recognize that many physical and psychological diagnoses are the consequence of stress. This led the PAC to conclude that “stress can contribute to a broad range of physiological and psychological illnesses. Stress is likely to be an important contributing factor to the broad range of illnesses currently being reported by Gulf War veterans” (p. 125).

We note with great interest the PAC’s statement that decades of clinical observations demonstrate a causal connection between stress and many physical and psychological diagnoses. For decades, the VA has denied any connection between service-connected Post Traumatic Stress Disorder (PTSD) and most physical or psychological disabilities. Veterans have routinely been unsuccessful in attempts to obtain service connection for mental and physical disabilities as secondary to PTSD. Why are these claims being denied if decades of clinical observations show a causal connection between stress and physical ailments? Congressional oversight in this area would clearly be appropriate and we urge this Committee to exercise that authority.

We also note with interest that, if the PAC’s assessment that stress is an important contributing factor to the current illnesses suffered by Persian Gulf veterans, then the current argument surrounding the expansion of the two-year presumptive period would appear to be meaningless. If, in fact, these illnesses are caused due to the stress experienced by these veterans while in military service, then service connection can be established at any time post service. Clearly, additional research in this area must be undertaken.

As scientific/medical researchers continue to search for the answer to the nagging question of Persian Gulf illness, our Nation must not forget that these veterans and their families are suffering because of the veteran’s deployment to the Persian Gulf. Accordingly, this Committee must continue to seek answers to help explain the mystery surrounding these unexplained ailments and to ensure that these veterans receive adequate compensation and appropriate medical care.

DAV concurs with the PAC's assessment that our Government should learn from its mistakes to help it avoid future post-conflict health concerns. Some of the areas that the PAC looked at in this regard were record keeping, communications, outreach, and follow-up services. The PAC noted that better record keeping and data collection were needed. It was noted that DoD had been responsive to the PAC's initial recommendations about medical treatment policies governing pre-, during, and post-deployment of U.S. troops; however, DoD was not responsive to its recommendation that DoD should undertake a thorough health evaluation of a large sample of troops to enable better post-deployment medical epidemiology. We concur that having accurate baseline data would help to resolve many post-conflict health concerns. We would encourage DoD to take the necessary steps to ensure that better record-keeping and data collection methods are put in place in the near future.

DAV firmly believes that our Nation owes the highest duty to the men and women of our Armed Forces to ensure their protection from diseases and illnesses endemic to that area of the world where they will be deployed. However, we do not believe that the men and women of our Armed Forces should be subject to experimental drugs without their full knowledge and informed consent. The delegates to our last National Convention, held in New Orleans, Louisiana, July 28-August 1, 1996, passed resolution number 238, opposing any authorization of use of members of the Armed Forces for human experimentation without their knowledge and informed consent. There is a definite line between using our military forces as guinea pigs to test the effects of harmful and injurious substances and wanting to protect the members of our Armed Forces from known diseases and illnesses by providing them with drugs or vaccines which may not be fully approved by the Food and Drug Administration. Accordingly, we support the PAC's recommendation that DoD develop enhanced orientation and training procedures to alert service personnel that they could be required to take such investigational drugs or vaccines, and we would further suggest that these drugs and vaccines not be given without the full knowledge and informed consent of the service member.

Concerning outreach, the PAC noted that VA's Vet Centers and Persian Gulf Family Support Program were able to quickly mobilize to provide comprehensive outreach services. In fact, it was further noted that they offered a more targeted and direct approach than subsequent DoD or VA efforts which focused on hotlines and public service announcements. We also concur with the PAC's assessment that effective risk communication requires a dialogue, a two-way flow of information, opinions and perception, and we would encourage DoD and VA to strive to provide avenues for veterans to get feedback to DoD and VA decision makers.

With respect to follow-up treatment, the PAC notes that follow-up treatment is usually problematic. It is noted that staffing constraints often result in long delays in scheduling appointments and that psychiatric staffing is particularly overloaded at some facilities. Additionally, many veterans receive follow-up care from a number of physicians, both government and private sector, and no single case manager is responsible for their care.

In the past, DAV has noted that there is a lack of coordination within the VA. VA health care interventions were organized to respond to symptoms rather than focus on possible underlying etiology. No single VA medical person had the "big picture" of a veteran's multiple symptoms. We have found that if a veteran presents him or herself to a VA medical clinic with a number of different symptoms, he or she is referred to each clinic that handles the specific symptom. In other words, a veteran suffering from headaches, rashes and a gastrointestinal disorder is sent to three different clinics. Sometimes, by the time the veteran is seen, the symptoms have disappeared, only to return at a later date. Coordination of care and disease tracking would facilitate the overall understanding of the episodic, as well as interrelational aspects of the medical problems reported by Persian Gulf veterans. Accordingly, a single case manager would not only benefit the veteran, but would also serve to provide necessary coordination of care and disease tracking.

The PAC report also focuses on reproductive health services, noting that the VA currently lacks the authority to provide benefits or services on the basis of adverse health effects in children, even if the effects are shown to result from their parents' service experience, with the exception of children with spina bifida born to Vietnam veterans who served in-country. We

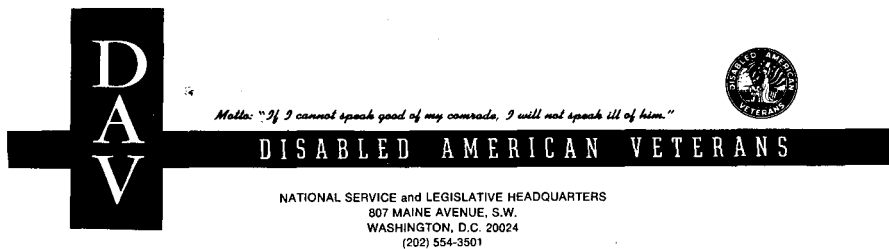
note that funding for benefits and services provided to Vietnam veterans' children who were born with spina bifida was derived from the savings generated from the amendment to section 1151 of title 38, United States Code following the Supreme Court decision in the *Gardner* case. Unfortunately, \$500 million in savings resulting from that amendment is going to programs other than those designed to assist veterans and their dependents. Only \$250 million of the estimated \$750 million savings from the *Gardner* case was used to fund the provisions for spina bifida. The other \$500 million will go to general deficit reduction, instead of being used for other VA programs or new benefits. Should Congress decide to give VA authority to provide benefits or services to the children of Persian Gulf veterans because of adverse health effects resulting from their parents' service experience, current VA programs and benefits will have to be cut in order to provide these new services. Therefore, we call upon this Committee to assist us in returning the excess *Gardner* funds to VA for use by the VA to implement or enhance programs and/or benefits.

In conclusion, let me state that the PAC report has offered important suggestions and recommendations with regard to dealing with the current problems in health care and outreach needs of Persian Gulf veterans. Additionally, the PAC report provides some needed insight into avoiding future post-conflict medical concerns. Unfortunately, we are not provided with any concrete answers as to what is causing Persian Gulf illness. Although the PAC has concluded that it is unlikely that the health effects reported by Persian Gulf veterans are the result of the numerous identified environmental hazards these veterans were exposed to in the Persian Gulf, DAV is still not convinced of this fact. While we do not have the scientific and medical expertise to contradict the PAC's assessment, which is reportedly based on numerous tests and studies as cited in the report, we are not convinced of the soundness of the conclusions reached by the PAC, particularly in light of the contradictory evidence that continually surfaces from physicians around the country who have had good results in treating Persian Gulf veterans suffering from various illnesses. Additionally, it is difficult for us to understand how valid tests and studies could find that the level of pollutants from oil well fires and smoke was lower than anticipated and "did not exceed those [levels] seen in urban air in a typical U.S. industrial city" (p. 100). The eyewitness accounts of veterans and photos would seem to contradict these findings.

Mr. Chairman, we call upon this Committee, the entire Congress, VA, DoD, Health and Human Services, and all other departments and agencies involved with Persian Gulf illness to continue to seek answers to explain the mystery surrounding the illnesses suffered by Persian Gulf veterans. Those brave men and women who served this Nation in the Persian Gulf deserve no less.

In closing, I would again emphasize that a presumptive period for service connection for undiagnosed illnesses must be open-ended until we are able to determine a cause or causes of the undiagnosed illnesses. Once this question has been answered, then a definitive presumptive period can be established, if appropriate.

This concludes my statement. I would be happy to answer any questions you or members of the Committee may have.



DISCLOSURE OF FEDERAL GRANTS OR CONTRACTS

The Disabled American Veterans (DAV) does not currently receive any money from any federal grant or contract.

During fiscal year (FY) 1995, DAV received \$55,252.56 from Court of Veterans Appeals appropriated funds provided to the Legal Service Corporation for services provided by DAV to the Veterans Consortium Pro Bono Program. In FY 1996, DAV received \$8,448.12 for services provided to the Consortium. Since June 1996, DAV has provided its services to the Consortium at no cost to the Consortium.

Joseph A. Violanto, Esq.
DISABLED AMERICAN VETERANS
Deputy National Legislative Director

807 Maine Ave. SW
 Washington, D.C. 20024

Phone (202) 554-3501
 Fax (202) 554-3581

EDUCATION:

1981 Juris Doctorate, University of La Verne, College of Law
 1975 Bachelor of Arts, History and Political Science, University of New Mexico

EMPLOYMENT:

1996-Current *Deputy National Legislative Director, Disabled American Veterans (DAV)*
 1992-1996 *Legislative Counsel, DAV*
 Assist the National Legislative Director establish and implement legislative goals; prepare and present written and oral testimony to committees/subcommittees of the US Congress; meet with members of Congress and their staffs to advance the goals of the DAV and disabled veterans; meet with Department of Veterans Affairs (VA) policy makers to discuss issues; analyze proposed legislation and VA's budget and appropriation, including preparation of written recommendations for the *Independent Budget for Veterans Affairs*; prepare bulletins, memorandums and letters regarding grassroots lobbying efforts; and provide general legal advice to the DAV.

1990-1992 *Staff Counsel, DAV*
 Reviewed and evaluated veterans' appeals for judicial review; researched and applied legal and medical issues; prepared legal briefs and other legal pleadings; prepared and presented oral arguments; negotiated and settled cases.

1985-1990 *Attorney, Department of Veterans Affairs, Board of Veterans' Appeals*
 Reviewed and evaluated veterans' claims for appellate adjudication; applied governing statutes and regulations to the legal and medical facts presented; and prepared written decisions in each case.

1981-1985 *Attorney, Sole Practitioner*
 Interviewed clients; researched legal issues; prepared legal pleadings; argued law and motion matters; and evaluated, negotiated and settled clients' cases.

ORGANIZATIONS AND AFFILIATIONS:

Member, State of California and District of Columbia Bars
 Member, Presidential Delegation (POW/MIA's) to Southeast Asia, March, 1996
 Co-chair, Veterans' Appeals Committee, Federal Circuit Bar Assoc., 1992-1996
 Co-chair, Legislative Committee, Federal Circuit Bar Assoc., 1996-present
 Vice chair, Veterans' Benefits Committee, American Bar Association, 1991-present
 At-large board member, Veterans' Law Section, Federal Bar Association, 1991-1992
 Life member, Disabled American Veterans, Chapter Commander, 1990-1991
 Life member, Veterans of Foreign Wars, Post Commander, 1984-1985
 Life member, 3d Marine Division Association, Chapter Secretary, 1986-1987
 Member, American Legion, Marine Corps League, and 2nd Bn, 4th Marines Assoc.
 Member, Knights of Columbus, Fourth degree
 Member, National Italian-American Foundation, Council of 1000
 Member, Geriatrics and Gerontology Advisory Committee, Dept. of Veterans Affairs
 Board of Directors, Bowie Cable TV, 1992-1994
 Member, Bowie Cable TV City Council Advisory Committee, 1989-1991
 Co-host, *Veteran's Forum*, Bowie Cable TV, 1991-1994

Testimony of Mr. Jeffrey S. Ford,
Executive Director, National Gulf War Resource Center,
before the
U.S. House of Representatives Veterans Affairs Committee
February 11, 1997

Mr. Chairman, Members of the Committee,

I want to thank you for inviting me to testify today on behalf of the National Gulf War Resource Center on issues relating to the illnesses being suffered by the veterans of the Gulf War and my concerns over the conclusions reached by the Presidential Advisory Committee on Gulf War Veterans' Illnesses.

The mission of the Presidential Advisory Committee final report consists of:

- an evaluation of the governments response to Gulf War veteran's illnesses;
 - an evaluation of available data on the nature of Gulf War veteran's illnesses;
 - an evaluation of available data on the health effects of Gulf War risk factors.
- (Executive Summary)

In it's evaluation of the governments response, the report conclude,

"Effective risk communication is essential to the government's credibility on Gulf War veterans' illnesses, but DOD and VA have not seriously attempted to educate veterans about health effects of service in the Gulf War or to establish a dialogue concerning research programs relevant to veterans' concerns."(18)

"Most DOD and VA outreach efforts concentrate on publicizing the clinical evaluation programs and then referring participants to them." "...these efforts do not fully educate veterans or sufficiently build their trust that the government's efforts to help them are comprehensive."(14)

"DOD and VA have not established clear pathways for veterans to provide feedback about clinical programs and/or about concerns regarding exposures; nor have they canvassed the Gulf War veterans' community regarding better methods of communication. It appears the only way in which a veteran could provide feedback would be through contact with the clinical personnel at local VAMCs or military hospitals. This, however, does not appear to be a likely route for transmitting concerns to decision makers."(15)

We can assure you this is and has been a serious problem from the start. The report also concludes,

"In such cases, trust, credibility, interaction, and community involvement are key to successful risk communication-but it is not clear whether DOD or VA will have personnel in place to conduct effective risk communication when findings from various reports are ready for dissemination."(16)

"The outreach initiative of VA's Persian Gulf Family Support Program was an effective method of communicating information about Gulf War veterans illnesses in particular the established government

clinical programs to veterans, Reservists, National Guard members, and local communities. The program used trained, knowledgeable personnel in the field to "...deliver specific information directly to Gulf War veterans."(18)

"More than 2,800 outreach briefings were conducted for approximately 70,000 persons, and approximately 22,000 PGFSP outpatient visits were made by veterans and family members nationwide. Funding for the program ended September 30, 1994. Some VAMCs continued to fund aspects of PGFSP, incorporating them into the facility's general budget. Most coordinators, however, returned to their original positions, and after the program ended, spouses and children had to contact Vet Centers to receive free counseling services."(11)

We recommend that the VA be given appropriate legislative authority and funding to deliver these services.

In November of 1995 the PAC began visiting these VA and DOD medical facilities:

VA Medical Center, Washington, DC (Referral Center; Phases I and II)

VA Medical Center, Durham, NC (Phases I and II)

VA Medical Center, Houston, TX (Referral Center; Phases I and II)

VA Medical Center, Indianapolis, IN (Phases I and II)

Naval Medical Center, San Diego, CA (Referral Center; Phases I and II)

Walter Reed Army Medical Center, Washington, DC (Specialized Care Center;
Phases I and II)

Eglin Air Force Base, Ft. Walton Beach, FL (Phase I)

University of Louisville Medical Center, Louisville, KY (CCEP contractor for Fort
Knox; Phases I and II)(21)

By the very nature these are some of the better facilities treating Persian Gulf illnesses and does not reflect a true representation of the level of care nationwide. Yet, the PAC found serious problems even at these facilities. At one referral center it was noted that,

"Delays of three months or more are not uncommon"(22) And,

"In contrast to the extensive knowledge of staff assigned directly to Gulf War-related programs, the knowledge level of staff not specifically assigned to the Registry or CCEP at both VA and DOD medical facilities was problematic. For example, the existence of the CCEP was largely unknown among staff at the VA facilities we visited."(24)

"Clinical staff not directly involved in VA's Registry and DOD's CCEP are not well informed about the programs."(28)

"At the time of the Committee's site visits, some staff at the VA medical facilities complained they were receiving less information about the program from VA Central Office than they felt they needed."(24)

"VA does conduct periodic interactive video teleconference sessions on Gulf War health topics for clinical and social work staff, but this format is designed for staff education, not as a formal, publicized mechanism of interaction with veterans and other members of the public."(15)

"There have been scattered Continuing Medical Education (CME) programs for DOD and VA medical facility staff about the government's Gulf War programs, but these are intermittent, usually limited to a single department, and not well attended."(24)

In fact I personally attended the latest of the teleconferences and myself and a social worker from the Vet Center were the only ones to attend out of the entire staff of the VAMC in Kansas City. I was assured a tape of the latest conference was available in the VAMC library for staff to check out. To date I am the only person to have checked out the tape since it was aired in October of 1996, in fact neither the PG Registry coordinator at Kansas City nor Columbia, Missouri VA had seen it or cared to.

The Committee fails to mention that many program coordinators also conduct Agent Orange as well as Compensation and Pension appointments and exams overburdening the often single individual therefore GW Registry participants receive the least consideration.

"The Committee heard public comment at each meeting citing insensitive attitudes on the part of staff at both DOD and VA medical facilities."(24)

"Frequently, these reports by veterans and their families centered on a dismissive or cynical approach to the veterans' problems-i.e., the message received was that problems were "not real" or "all in your head." Veterans who sought care after the Gulf War but before the establishment of the Registry and CCEP appeared to suffer most from this treatment."(24)

We wish to know where are those veterans now and how can the VA hope to repair this breach of trust and encourage these veterans to return to the system.

And then this most interesting comment from the committee,

"Most facilities did not designate a separate clinic space for Phase I evaluations, seeking to mainstream participants as much as possible and reduce the possibility of symptom sharing. Some facilities (e.g., VAMC, Durham, NC), have set aside specific clinic hours for the Gulf War evaluations and report no evidence of symptom sharing among their group of veterans. With the significant reduction in numbers of Gulf War veterans seeking evaluation, all clinical spaces we visited are more than adequate to handle current demand.

As was noted earlier, however, the extent to which this remains true is unclear, given recent heightened media attention to Gulf War illnesses."(23,24)

We wonder if the PAC assumes that over 100,000 ill Gulf War veterans from across the U.S. have shared their symptoms amongst themselves to conspire against the VA. From the first small group of Indiana veterans who came forward in 1992, a group that was dismissed as malingerers, until today, the symptoms reported have not changed. This seems to negate claims of so-called symptom sharing. This government trend of discounting reports from our own soldiers in favor of reports from Iraqi deserters, foreign governments, U.N. officials and bureaucrats is disturbing.

"To complete its work on medical and clinical issues, the Committee assessed whether Gulf War veterans currently receive access to quality medical care under programs established by the government for their care. We specifically examined the availability of reproductive health care because of the high degree of concern expressed by Gulf War veterans and their families in this regard. Finally, the historically important role of postconflict stress reactions on the health of veterans led us to give particular scrutiny to this issue."(20)

"VA has no policies in place to systematically address the concerns of Gulf War veterans regarding reproductive health."(26)

"Both the Registry and CCEP are treatment programs, not research protocols, but the data have been used to generate research hypotheses."(21)

"This Committee and others have judged the protocol to be an excellent tool for diagnosing illness."(47)

We must question then, what is considered to be a useful tool for dealing the with undiagnosable illnesses?

"Despite the general medical adequacy of the VA and DOD evaluation programs, followup treatment-particularly where mental health visits are involved are problematic."(25)

"Follow-up treatment of active duty veterans also is made more difficult by command resistance to granting the necessary time off to maintain an adequate treatment program. This is true for all chronic illnesses, but especially so for psychological diagnoses."(25)

"Staffing constraints often result in long delays in scheduling appointments in some specialties. Psychiatric staffing is particularly overloaded at some sites."(25)

Yet, the PAC asserts that,

"DOD and VA have implemented innovative programs to help veterans cope with combat-related stress."(28)

And finally,

"The Committee found that, overall, high-quality health care is [being] provided."(47)

"Ninety percent of separating active duty service members attend Transition Assistance Program (TAP) workshop briefings conducted jointly by DOD, VA, and DOL [Department of Labor]. VA benefits briefings during the TAP workshop could be an effective method of outreach about DOD and VA programs for evaluating Gulf War veterans illnesses, yet there is no evidence their clinical programs receive mention."(17)

Also,

"It is plausible that briefings include information about DOD and VA clinical programs designed for evaluating Gulf War veterans and their families, but no evidence exists to suggest these programs are mentioned."(12)

"In its coordinated risk communication plan, DOD and VA should engage veterans service organizations as intermediaries and include personnel in leadership positions, such as senior enlisted personnel (for active duty military) and state veterans' service officials in the effort to establish an efficient information exchange process where veterans receive accurate information and the departments receive valuable feedback on clinical programs, health concerns, and communication efforts."(52)

While we welcome the aspect of being a part of the decision making process, we also question if the PAC is recommending that veterans service organizations should conduct the outreach responsibilities of the Federal Government, if so, will the government offset some of the costs? How will the participating organizations be selected.

"While VA and DOD have encouraged their principal investigators to convene and consult scientific advisory committees, they have not taken serious steps to encourage the formation and use of public advisory committees. Although public advisory committees will be recommended for epidemiological studies recently funded by DOD and VA, their use is given low priority by program administrators. The Committee believes this practice is unfortunate because, as is evidenced by the experience of the Centers for Disease Control and Prevention (CDC), public advisory committees can greatly facilitate incorporation of veterans' concerns into study design, dissemination of results, and risk communication."(47)

"DHHS [Department of Health and Human Services] has historical strengths in public health (e.g., CDC) that are brought to bear in this effort. However, except for the National Institute of Environmental Health Sciences, DHHS's many basic biomedical research intramural activities and extramural projects that could contribute substantial expertise to Gulf War health issues are peripherally involved in RWG's activities, if at all."

"Currently, stress is the risk factor funded for the greatest fraction of total studies 32 studies (30 percent). Stress is not well understood in terms of diagnoses, physiological sequelae, and effective prevention and treatment strategies; yet it is likely to be an important contributing factor to illnesses currently reported by Gulf War veteran."(34)

We find that since the majority of studies funded and nearly half the studies completed to date were stress related it's not surprising the Committee found *stress* to be an "important contributing factor." It is also the subject area in which DOD and VA have provided the most information.

"DOD, DHHS, and VA should recommend their principal investigators use public advisory committees in designing and executing epidemiological studies of Gulf War veterans' illnesses."(15)

"Given that the Food and Drug Administration's (FDA) Interim Final Rule permitting a waiver of informed consent for use of unapproved products in a military exigency is still in effect, DOD should develop enhanced orientation and training procedures to alert service personnel they may be required to take drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of chemical and biological warfare."(52)

"The Committee remains seriously concerned about the amount of time currently approaching six years-FDA is taking to open the process to public comment."(27)

We are also concerned that the FDA waiver process currently being used permitting DOD to evade legal safety requirements in the administration of experimental drugs, continues to place members of our armed forces at risk.

"DOD's lack of response in this highly sensitive area contributes to the perception of many that U.S. troops were inappropriately subjected to investigational drugs or vaccines during the Gulf War."(27)

This perception does exist in the eyes of the Gulf War veteran community. As a result rumors and fact intermingle, further eroding the credibility of both DOD and VA.

"DOD has made its congressionally mandated Persian Gulf Registry of Unit Locations available to government and private researchers, but the database lacks the precision and detail necessary to be an effective tool in the investigation of exposure incidents. More to the point, the unit locator database has failed in its application to the single CW agent incident investigated by DOD in any detail to date, e., Bunker 73 and the pit at Khamisiyah."(29,30)

"... the Committee concludes the unit locator has not proved to be a valuable tool for investigating exposure incidents.(30)

Therefore we believe it should not be used to determine service connection based on a veterans' exposure at a "supposed" unit location.

"In testimony and submissions to this Committee, DOD has taken the position that chemical agent exposures can be confirmed only through physical symptoms. The Committee believes this approach is analytically flawed and that medical symptoms should not drive a determination of presumed exposure/nonexposure."(41)

"During the air war, the nearest U.S. personnel were in Rafha, Saudi Arabia more than 400 km from Muhammadiyat and Al Muthanna."(39)

Or less than 245 miles from Muhammadiyat and Al Muthanna depending on from what perspective you see it, as I was personally at Rafha during the air war. Even at these locations chemicals sensors were detecting low-level airborne quantities of chemicals warfare agents known to be stored in facilities bombed just hours before.

Yet, the PAC reports,

"The Czech detections represent un rebutted evidence of the presence of CW agents at these sites, and low-level exposure-at the detection sites-must be presumed."(41)

"This inability to identify a source for the Czechdetected CW agents precludes modeling the range of exposures around the detection sites. CW agents also were not detected by U.S. troops sent to confirm the Czech findings. Currently, it is not possible to identify lowlevel exposure of any U.S. troops associated with these two Czech detections."(41)

"The best evidence available, indicates theaterwide contamination with CW agent fallout from the air war is highly unlikely."(40)

"(The general population exposure is a threshold at which one would not expect to see characteristic signs and symptoms of CW agent exposure.)"(39)

"And, some veterans have not received satisfactory explanations for wartime incidents they believe involved chemical weapons."(39)

The committee offers no hypothesis on where the agents repeatedly detected by the Czechs came from.

"The Committee's review of U.S. Army hospital admissions records identified only one admission for anthrax (a disease indigenous to the Gulf region) and none for botulinum poisoning. Stateside laboratory analyses also have not indicated BW agents were present in the KTO. Reports of dead animals that could have succumbed to biological warfare agents have been investigated by DOD, and the evidence does not implicate biological warfare."(38)

"Finally, Iraqi officials have denied any use of biological weapons during Operations Desert Shield/Desert Storm."(38)

"Thus, the best evidence available to the Committee indicates U.S. personnel were not exposed to biological warfare agents during the Gulf War."(38)

"This conclusion is based on imperfect information."(38)

According to the PAC,

"DOD has conducted a superficial investigation of possible chemical warfare agent exposures that is unlikely to provide credible answers to veterans' and the public's questions."(46)

"To ensure credibility and thoroughness, further investigation of possible chemical or biological warfare agent exposures during the Gulf War should be conducted by a group independent of DOD."

Yet the Pentagon will continue to be the lead investigative agency. We question the Committees' ability to provide credible answers in part because their report relies too heavily on information from agencies whose efforts have been criticized by the PAC as "superficial" and "inadequate" and because

it operates using consensus management. This is a useful tool for looking at issues surrounding quality of VA care, but inappropriate for evaluating scientific research. In science, if several hypotheses are offered, it is more likely that one of them is accurate rather than a newly formed compromise hypothesis. Most of the individuals on the panel are unqualified in the scientific disciplines under consideration. In fact, many are not scientists at all. Yet, these individuals are drawing conclusions that have serious implications on the health and safety of our soldiers.

Therefore we request that any further investigation be conducted independent of any government agency and that all records and evidence the PAC now holds be turned over to Congress for a proper and open investigation.

"DOD has made progress in improving medical record keeping in theater and stateside, but increased and sustained commitment from DOD's Joint Chiefs of Staff and Commanders in Chief will be necessary for current prototypes and plans to be fully and successfully integrated and implemented."(28)

The PAC also notes,

"DOD officials at the highest echelons, including the Joint Chiefs of Staff and the Commanders in Chief, should assign a high priority to dealing with the problem of lost or missing medical records."(52)

We are concerned as well for all missing and or destroyed records concerning the Gulf War. As many of these documents were classified, it seems appropriate that Congressional oversight hearings also be held on the disposition of the records.

"The government should plan for further research on possible longterm health effects of low-level exposure to organophosphorus nerve agents such as sarin, soman, or various pesticides, based on studies of groups with well-characterized exposures. Depleted uranium munitions are likely to be used in future conflicts involving U.S. service personnel."(54)

"To fully elucidate the health effects of depleted uranium munitions, VA should conduct research that compares the health status of individuals with embedded fragments of DU shrapnel with appropriate control groups."(54)

Why does the VA leave radioactive shrapnel in its' veterans so they can be studied?

What about the exposure to 350 tons of spent DU that we were exposed to, breathed in and ingested, when will we receive a whole body test?

"Openness in oversight activities-including public access to information and veteran participation-public notice of meetings, opportunity for public comment, and regular reporting are essential. Full public accountability is critical."(55)

"We reviewed the limited data regarding the likelihood or extent of exposure to pesticides, chemical and biological warfare agents and the vaccines and drugs used to protect against them, endemic

infectious diseases, depleted uranium, oil well fire smoke and other petroleum products, and psychological and physiological stress.”(5)

“Available data are sparse. Generalizable conclusions about the nature and extent of illness will come only from population-based epidemiologic studies that will not be completed until well after this Committee disbands.”(5)

“Our review of outreach, medical and clinical issues, research, and coordination resulted, principally, in findings and recommendations to help the government finetune its efforts. The notable exception to our generally positive report comes from our evaluation of the government's efforts to investigate possible exposures of veterans to chemical and biological warfare agents. In this instance we intend our recommendations to be constructive, but the Committee's findings are severe and unequivocal.”(5)

“...our recommendations are many, they are offered to improve the government's generally commendable response. Their number and scope should not be viewed as a wholesale condemnation or cause for a complete overhaul of the government's approach to addressing the health concerns of Gulf War veterans.”(50)

The Secretaries of DOD, DHHS, and VA head the Coordinating Board. The Coordinating Board's three primary missions are:

- to provide all veterans the complete range of health care services necessary for medical problems that might be related to deployment in Operations Desert Shield/Desert Storm;

Has this been done? No.

- to develop a research program that will result in the most accurate and complete understanding of the types of health problems being experienced by Gulf War veterans,

Has this been done? No.

- veterans and the factors that have contributed to these problems; and to develop clear and consistent guidelines for the evaluation and compensation of disabilities related to Gulf War service.(46,47)

Has this been done? No.

- The mission of the Presidential Advisory Committee final report consisted of, an evaluation of the governments response to Gulf War veteran's illnesses;

Was this done? Somewhat.

- an evaluation of available data on the nature of Gulf War veteran's illnesses;

Was this done. Much government data was considered, however, outside independent data did not by any means receive equal consideration.

- an evaluation of available data on the health effects of Gulf War risk factors.

Has this been done? No. Six years after the war we still have no broad based epidemiological data on the nature of the illnesses suffered by the veterans and their families.

Mr. Chairman, it is now six years since the Persian Gulf War. We now know that the veterans were exposed to a number of hazardous compounds which alone or in combination may be causing illnesses similar to those being reported. The government still does not accept that these exposures may have resulted in our illnesses and we are still debating whether or not the Pentagon is involved in a cover-up.

It is time to move on. Time to presume that these exposures occurred. Time to initiate appropriate broad based epidemiological studies of our veterans and their families. Time to enlist the support of independent scientists and researchers concerned about curing disease. Not those who are more concerned about protecting their agencies bureaucratic interests.

Finally, it is time that we stop investigating the investigation and move on to provide quality care to our veterans and a review of the safety measures we implement to protect those still on active duty.

Mr. Chairman I thank you.

Neither myself or the National Gulf War Resource Center, Inc. has received Federal grants or funds in the past two years. (Per regulation)

Reference Cited

Presidential Advisory Committee on Gulf War Illnesses: Final Report
(Washington, DC: U.S. Government Printing Office, December 1996)

TESTIMONY OF DAVID TROY SMITH
TO THE
HOUSE VETERANS' AFFAIRS COMMITTEE
ON
FEBRUARY 11, 1997

GOOD AFTERNOON HONORABLE CHAIRMAN AND COMMITTEE MEMBERS.
THANK YOU FOR THE OPPORTUNITY TO TESTIFY.

I AM DAVID TROY SMITH, A FORMER UNITED STATES MARINE NCO WHO WAS HONORABLY DISCHARGED ON JULY 12, 1991, AFTER NINE YEARS OF SERVICE. THIS ENDED WITH 9TH COMM BN, 1ST(SRIG), SURVEILLANCE, RECONNAISSANCE, INTELLIGENCE GROUP IN OPERATION DESERT SHIELD AND STORM FROM AUGUST 10, 1990 TO APRIL, 1991.

PRIOR TO DEPLOYMENT IN THE PERSIAN GULF, I PARTICIPATED IN THE MARINE CORPS ATHLETIC PROGRAM FROM 1986 THROUGH 1990. DURING THIS PERIOD I EARNED, FROM THE DEPARTMENT OF DEFENSE, FOUR CERTIFICATES OF ACHIEVEMENT FOR ATHLETIC ENDEAVORS AND SIX ALL-MARINE CERTIFICATES FOR WRESTLING, POWER LIFTING, AND TRACK AND FIELD; INCLUDING COMPETITION AT FOUR U.S. NATIONAL CHAMPIONSHIPS AND FIVE MILITARY NATIONAL CHAMPIONSHIPS. I MAINTAINED UNIT INTEGRITY WITH MICROWAVE COMMUNICATIONS AS A SENIOR NCO IN THIS MOS WITH A SECRET SECURITY CLEARANCE. MY CAREER BEGAN AS A MARINE SERIES HONOR GRADUATE. WITH THESE ACCOMPLISHMENTS BEHIND ME, I FELT MY PERSONAL MISSION IN THE UNITED STATES MARINE CORPS WAS COMPLETE.

CIVILIAN LIFE LOOKED GOOD. I SECURED A JOB AS MANAGER OF A WORLD GYM IN NEW JERSEY WHERE I WON THE STATE POWER LIFTING CHAMPIONSHIP FOR 242 LBS. AFTER MOVING TO IDAHO, I SECURED A JOB AS WOODSHOP SUPERVISOR FOR AN INTERNATIONAL ARCADE GAME DISTRIBUTOR, ALL THE TIME TRYING NOT TO RECOGNIZE THE MEDICAL PROBLEMS--NOT WANTING THEM TO INTERFERE WITH MY OBJECTIVE--THAT HAVING A WIFE AND CHILDREN WHO'S MOTHER COULD STAY AT HOME.

NOW I SIT BEFORE THIS COMMITTEE A 32-YEAR-OLD FATHER OF TWO, V.F.W. SERVICE OFFICER AND IDAHO STATE COMMANDER FOR THE DESERT STORM JUSTICE FOUNDATION. I AM OFFICIALLY BANKRUPT, TOTALLY DISABLED BY S.S.A., UNABLE TO RECEIVE VOCATIONAL REHABILITATION

FROM SSA AND VA, AND UNTIL RECENTLY, HAD NO COMPENSATION FROM THE VETERAN'S ADMINISTRATION! MY HOPE IS TO BRING TO LIGHT THE SUFFERING THAT MANY OF OUR UNITED STATES VETERANS CONFRONT DAILY AND THAT SOMETHING AS POWERFUL AS THIS COMMITTEE CAN AFFECT THE NECESSARY CHANGES TO ENSURE AGGRESSIVE TREATMENT AND COMPENSATION FOR ALL ILL VETERANS.

THE TESTIMONY I AM GIVING IS A BRIEF HISTORY OF THE PAST FIVE YEARS IN MY BATTLE WITH THE VETERANS ADMINISTRATION. SOME SIGNIFICANT PEOPLE ARE SENATOR KEMPTHORNE'S OFFICE, CONGRESSWOMAN CHENOWETH, THE AMERICAN LEGION AND IT'S GULF WAR TASK FORCE, ESPECIALLY MR. CARROLL WILLIAMS, AND ART BREST FOR BRINGING THE PROBLEMS TO THE ATTENTION OF THE VA CENTRAL OFFICE IN WASHINGTON, D.C.-- WHO NOW ARE AWARE OF THE PROBLEMS AND HAVE WORKED QUICKLY TO RESOLVE THE SITUATION.

DURING MY DEPLOYMENT TO THE PERSIAN GULF, I WAS WEIGHED ON A FREIGHT SCALE TO VERIFY THAT MY WEIGHT WAS 263 LBS. HOWEVER, WITHIN TWO WEEKS OF THE GROUND WAR I DEVELOPED HIGH FEVER, DIARRHEA, AND A SEVERE WEIGHT LOSS WHICH ENDED IN A 24-HOUR LOSS OF CONSCIOUSNESS AND WHEN I AWOKE MY SLEEPING BAG WAS SOAKING WET. I WAS FACE DOWN AND HAD DEFECATED ON MYSELF. THIS INCIDENT CAME WITHIN 72 HOURS OF BEING FORCED TO RECEIVE INJECTIONS FROM THE BATTALION AID STATION (BAS) WHERE THEY TRIED TO FORCE ME TO SIGN A FORM THAT STATED: "BY SIGNING THIS FORM YOU RELIEVE THE U.S. GOVERNMENT OF ANY POSSIBLE SIDE EFFECTS OF THIS MEDICATION."

WHEN I DEPARTED THE PERSIAN GULF IN APRIL, 1991, THE BOWEL PROBLEM WAS SPORADIC AND MY WEIGHT WAS RETURNING TO NORMAL. I RETURNED TO THE UNITED STATES AND BEGAN PROCESSING FOR DISCHARGE. HOWEVER, THIS WAS DELAYED WHEN I WAS PLACED ON MEDICAL HOLD FOR STOMACH PROBLEMS. DURING THE INTERNAL MEDICINE CONSULT AT CAMP PENDLETON CA, IT WAS DETERMINED THAT IT COULD TAKE THREE MONTHS LONGER. TO ME THAT DID NOT SEEM SOMETHING A MARINE SHOULD DO. THIS WAS CONVEYED TO THE IM DOCTOR WHO ASSURED ME THAT IF I CHOOSE TO DISCHARGE THAT IT WOULD BE NOTED ON MY FINAL PHYSICAL AND IN MY MEDICAL RECORDS. I WAS ASSURED THAT THE VA WOULD TAKE CARE OF MY PROBLEMS SO LONG AS IT WAS DOCUMENTED. I AGREED TO GO TO THE VA

UPON DISCHARGE AND WAS RELEASED FROM MEDICAL HOLD BECAUSE THIS PROBLEM DIDN'T SEEM LIFE THREATENING, AND MY WEIGHT HAD RETURNED TO A POINT OF 255 LBS. I RETURNED TO MY UNIT AND FINISHED MY DISCHARGE PAPERWORK AND WAS TOLD THAT MY MEDICAL RECORDS WOULD BE OBTAINED BY THE VA ONCE I SOUGHT TREATMENT.

HAVING BEEN DISCHARGED IN JULY, 1991, I WAS EAGER TO GET ON WITH MY NEW LIFE. ALTHOUGH MY MEDICAL PROBLEMS BECAME MORE BOTHERSOME, I FELT AS A MARINE THAT HEADACHES AND DIARRHEA WERE TRIVIAL PROBLEMS TO BOTHER A DOCTOR FOR. BUT I WAS ADVISED BY AN AMERICAN LEGION POST COMMANDER AND VIETNAM VETERAN THAT THE MEDICAL PROBLEMS NEEDED TO BE DOCUMENTED BY THE VA. A NEW JERSEY STATE SERVICE OFFICER ARRANGED MY FIRST EXAMINATION WITH THE VA MEDICAL SYSTEM AT EAST ORANGE, N.J., IN SEPTEMBER, 1991 -- LESS THAN THREE MONTHS AFTER MY DISCHARGE. WHEN I ARRIVED FOR MY VISIT TO THE DOCTOR, IT TURNED OUT TO BE A COMPENSATION AND PENSION EXAMINATION. DURING MY EXAMINATION, THE DOCTOR FOUND NO REASON FOR THE HEADACHES BUT RECOMMENDED I SEE AN OPHTHALMOLOGIST AS PART OF THE EXAMINATION, WHO DETERMINED THIS WAS THE CAUSE OF MY HEADACHES, AND A PRESCRIPTION FOR GLASSES WAS ISSUED.

IN JUNE, 1992, I RECEIVED A LETTER AND CHECK FROM THE V.A. FOR 10% SERVICE-CONNECTED DISABILITY FOR HYPERTENSION, AND BACK PAY TO JULY, 1991. THE RATING SURPRISED ME AS NONE OF THIS WAS CONVEYED TO ME IN THE MEDICAL VISIT WITH THE DOCTOR, YET I ASSUMED THAT THE VA MUST KNOW WHAT THEY ARE DOING.

IN SEPTEMBER, 1992, I SOUGHT TREATMENT AT WALLA WALLA, WA VAMC BECAUSE AT THIS TIME THE BOWEL PROBLEM HAD TURNED INTO EXPLOSIVE DIARRHEA THAT MANIFESTED WITHOUT WARNING AND THE HEADACHES WERE SEVERE. I WAS SEEN BY A PHYSICIAN'S ASSISTANT WHO PRESCRIBED SALSANTE AND LOMOTIL. THE PROBLEMS CONTINUED AND I WAS ASSIGNED A PRIMARY PHYSICIAN. FROM SEPTEMBER, 1992, THROUGH JULY, 1994, I UNDERWENT NUMEROUS CONSULTATIONS WITH MENTAL HEALTH, OPHTHALMOLOGY, NEUROLOGY AND GASTROINTESTINAL; ALL WITH VARYING DIAGNOSIS FROM PTSD, HYPERTHYROIDISM, RAPID TRANSIT AND POST CONCUSSIVE HEADACHES, YET NONE WERE FOLLOWED UP BY MY PRIMARY CARE PHYSICIAN. DURING THIS TIME I UNDERWENT TWO COMPENSATION AND PENSION EXAMINATIONS AND THESE NOTED VARYING PROBLEMS. RESULTS WERE RECEIVED IN JULY, 1994,

FROM THE PERSIAN GULF REGISTRY PHYSICAL WHICH STATED: CHRONIC DIARRHEA ETIOLOGY UNKNOWN AND CHRONIC JOINT PAIN DESPITE LACK OF FINDINGS. THIS WAS THE LAST I HEARD FROM THE MEDICAL SIDE, YET MENTAL HEALTH ENCOURAGED ME TO ATTEND PTSD GROUP THERAPY. I DID NOT SEE THE NECESSITY FOR THERAPY BECAUSE FLASHBACKS, BAD DREAMS AND PROBLEMS ADJUSTING TO THE CIVILIZED WORLD WERE EXPECTED. FINALLY, IN SEPTEMBER, 1994, I COLLAPSED ON MY KITCHEN FLOOR TOO WEAK FROM THE SUDDEN PAIN AND DEFECATED ON MYSELF. MY WIFE FOUND ME AND BECAME VERY CONCERNED. THROUGH THE INTERVENTION OF SENATOR KEMPTHORNE'S OFFICE, I WAS GIVEN A MEDICAL APPOINTMENT WITHIN 24 HOURS AT WALLA WALLA VAMC FOR REFERRAL TO WEST LA VAMC PERSIAN GULF WORKUP CENTER. ONCE I WAS INFORMED MY REFERRAL WAS IN PROCESS, I BECAME CONCERNED AS TO WHAT WAS EXPECTED IN WEST LOS ANGELES AND HOW WOULD I SUPPORT MY WIFE AND TWO CHILDREN. UPON CONTACTING THE WALLA WALLA PERSIAN GULF COORDINATOR, HER RESPONSE WAS, "I COULD TRY APPLYING FOR WELFARE OR GO TO CHURCH, FAMILY AND/OR FRIENDS." I THEN CONTACTED MY REFERRING NURSE AND SHE DID NOT KNOW ANYTHING SO I WAS GIVEN THE NUMBER TO CONTACT THE PROGRAM DIRECTOR'S OFFICE IN WEST LA. THE INFORMATION HE CONVEYED WAS QUITE DISTURBING. HE TOLD ME THIS WAS A TEACHING HOSPITAL AND THERE WAS NOTHING THEY COULD DO FOR ME EXCEPT TRY AND DIAGNOSE MY MEDICAL PROBLEMS AND GATHER INFORMATION TO HELP OTHER GULF WAR VETERANS AND REFER ME BACK TO MY LOCAL V.A. HOSPITAL FOR TREATMENT. THIS IN MIND, I PREPARED TO DEPART, FIRST TAKING AN UNPAID MEDICAL LEAVE OF ABSENCE FROM MY POSITION. SECOND, I HAD TO ACQUIRE A MEDICAL AND GENERAL POWER OF ATTORNEY AND LIVING WILL. I THEN PACKED UP MY WIFE AND NEWBORN SON AND HEADED TO CALIFORNIA FOR WHAT WAS SUPPOSED TO BE A 14-21 DAY STAY IN THE HOSPITAL.

UPON ARRIVAL TO WEST LA VAMC ON OCTOBER 25, 1994, I IMMEDIATELY BECAME AWARE OF WHAT A TEACHING HOSPITAL WAS ABOUT. THE PROBLEMS I WAS FORCED TO DEAL WITH DURING MY ACTUAL 39-DAY STAY WERE NUMEROUS. A GOOD PORTION OF THE STAY I MAINTAINED A JOURNAL TO TRACK WHAT WAS HAPPENING. MY ROOMMATE WAS A 30-YEAR RETIRED ARMY SGTMAJ WHO WAS DYING OF CANCER AND HE INSTILLED A VERY STERN WARNING TO WATCH THE VETERANS ADMINISTRATION FOR PTSD THERAPY AND

ANY KIND OF NARCOTIC PAIN KILLERS. FROM THAT POINT MY EYES WERE WIDE OPEN. AT ONE POINT, MY WIFE HAD TO SEE THE DIRECTOR OF THE MEDICAL CENTER JUST TO HAVE THE DIETARY INSTRUCTIONS OF THE DOCTOR FOLLOWED. PRIOR TO MY DISCHARGE, I ASKED THE CHIEF OF ADMINISTRATIVE MEDICINE IF HE WOULD PLEASE GO THROUGH MY MEDICAL RECORDS WITH ME SO AS TO HELP ME UNDERSTAND MY MEDICAL CONDITION.

ON DECEMBER 2, 1994, I WAS DISCHARGED WITH SEVEN NOTED MEDICAL PROBLEMS AND NINE MEDICATIONS RANGING FROM MORPHINE TO PROZAC. THE LAST THING I DID WAS GO TO RECORDS AND SIGN A RELEASE OF INFORMATION FOR A COMPLETE COPY OF ALL MEDICAL RECORDS ONCE THEY BECAME AVAILABLE. AGAIN, SENATOR KEMP THORNE WAS INVOLVED JUST TO GET THE RECORDS TRANSFERRED AND MY COPY OF THE RECORDS WHICH CARRIED A STAMP THAT STATED: "THESE DOCUMENTS OR RECORDS (OR INFORMATION CONTAINED HEREIN) ARE DEEMED CONFIDENTIAL AND PRIVILEGED UNDER PROVISIONS OF 38 U.S.C. 3305 AND VA REGULATIONS 6500 THROUGH 6540, WHICH PROVIDES FOR FINES UP TO \$20,000 FOR VIOLATIONS."

UPON ARRIVAL BACK AT WALLA WALLA VAMC DECEMBER 8, 1994, WE HAD ANTICIPATED SOME PROBLEM ARRIVING BACK WITH ONLY A SINGLE DISCHARGE PAPER AND A PRIMARY PHYSICIAN WHO DID NOT THINK THAT I WAS SICK, AND PREVIOUS VERBAL CONFRONTATIONS WITH THE NURSE AND DOCTOR. I WAS MET BY A NURSE WHO TOLD ME THE ONLY THING THAT COULD BE DONE WAS TO SCHEDULE AN APPOINTMENT FOR 30 DAYS FROM NOW, JANUARY 8, 1995. I THEN INQUIRED ABOUT MY MEDICATIONS WHICH WOULD EXPIRE ON JANUARY 1, 1995, AND WAS ASSURED IF I CALLED IN THE PRESCRIPTIONS ONE WEEK PRIOR THEY WOULD BE REFILLED. WHAT SHE DID NOT SAY, HIS WAS AT THE DOCTORS DISCRETION. WHEN I RETURNED ON JANUARY 8, 1995, TO SEE MY PRIMARY CARE PHYSICIAN, MY RECORDS SUPPOSEDLY HAD NOT ARRIVED FROM WEST LA VAMC AND HE DID NOT AGREE WITH THE FINDING OF WEST LA HOSPITAL. THIS WAS HIS REASON FOR NOT RENEWING SOME OF THE MEDICATIONS. THE PROBLEM WITH HIS STOPPING MY MEDICATION FOR MORPHINE WITHOUT ANY WARNING WAS I HAD BEEN ON THIS STRONG NARCOTIC FOR TWO MONTHS. NEEDLESS TO SAY, MY WITHDRAWALS WERE QUITE UNPLEASANT. I CALLED DR. RONALD HAMM, WEST LA TO ASK FOR ASSISTANCE IN PROCESSING MY MEDICAL RECORD BECAUSE TREATMENT WOULD NOT CONTINUE UNTIL MY COMPLETE FILE WAS PRESENT.

HE ASSURED ME THAT THE RECORDS WERE IN ROUTE TO WALLA WALLA VAMC AND THE ONLY THING HE COULD DO WAS OFFER ME A DETOXIFICATION CENTER IN WEST LA. FEBRUARY 5, 1995, IS THE LAST TIME I SAW MY PRIMARY CARE PHYSICIAN BECAUSE HE FELT THERE WAS NOTHING ELSE THAT HE COULD DO FOR ME. MENTAL HEALTH CONTINUED TO OFFER TREATMENT AND I SELF-ADMITTED ON OCTOBER 2, 1995, DUE TO PERIODS OF MEMORY LOSS ACCOMPANIED BY VIOLENT ACTS. DURING THIS HOSPITAL STAY, I RECEIVED GROUP THERAPY ONCE A DAY FROM A NURSE AND NO OTHER TREATMENT EVEN THOUGH MORE WORKUPS WERE ORDERED. THE LAST TIME I RECEIVED ANYTHING FROM THE WALLA WALLA VA, WAS A LETTER TELLING ME THAT I WAS NOT ELIGIBLE FOR TREATMENT UNTIL SERVICE CONNECTED FOR MEDICAL PROBLEMS WAS ESTABLISHED. PTSD THERAPY WASN'T AVAILABLE ON FEE BASIS DESPITE THE 220-MILE ROUND-TRIP TO MY LOCAL VA HOSPITAL, BUT I COULD TRY THE SPOKANE VAMC. I TRIED TO SEEK TREATMENT AT THE SPOKANE, WA VAMC BUT ENDED WITH THE SAME RESULTS--NO TREATMENT UNTIL SERVICE CONNECTION IS ESTABLISHED. A PRIVATE DERMATOLOGIST WROTE A LETTER STATING THE DIAGNOSIS OF A BIOPSY TAKEN FROM LESIONS THAT HAD MANIFESTED ON MY FOREHEAD AND EYES. THIS PROMPTED A REFERRAL TO SEATTLE VAMC INFECTIOUS DISEASE CLINIC FROM MY PRIMARY CARE PHYSICIAN AT WALLA WALLA VAMC WHO STILL TO THIS DATE, FEBRUARY 11, 1997, I HAVE NOT SEEN FOR ANY MEDICAL EXAMINATION.

IN CLOSING: THE CHANCE TO PRESENT MY STORY BEFORE THIS COMMITTEE IS AN HONOR AND PRIVILEGE, YET I HAVE CONSIDERABLE CONCERNS THAT IT TAKES A HEARING BY THIS HOUSE COMMITTEE TO SHED LIGHT ON THE PROBLEMS THAT THOUSANDS OF VETERANS ARE ENCOUNTERING DAILY AFTER SERVICE TO THIS COUNTRY, MUCH LIKE MYSELF WHO CLEARLY NEEDED HELP TO ACQUIRE MEDICAL ATTENTION. THIS, FROM A SYSTEM THAT WAS ESTABLISHED, AS ABRAHAM LINCOLN STATED: "TO CARE FOR HIM WHO SHALL HAVE BORNE THE BATTLE, AND FOR HIS WIDOW AND HIS ORPHAN."

AGAIN, THANK YOU FOR THE OPPORTUNITY TO APPEAR BEFORE THIS COMMITTEE--IT WAS AN HONOR.

Statement
of
Derek E. Davis
before the
Committee on Veterans Affairs
House of Representatives
February 11, 1997

Mr. Chairman and Members of the Committee:

My name is Derek Davis. As a veteran of the Persian Gulf War, I appreciate the opportunity to testify today.

My service in the Gulf was as commander of the Army National Guard's 276th Military Police Company. My company was deployed to the Gulf in February 1991, after approximately a month's medical screening and final training at Fort Meade, MD. Our pre-deployment medical screening was very thorough (much more so than at separation after returning from the Gulf), and several men did not deploy because of health problems that were uncovered. Those who left for Saudi were in excellent health and top physical shape. Ours was a cracker-jack company which had served earlier overseas with distinction.

My company's mission in Saudi Arabia was to provide security for a large ammunition supply point (ASP Quarry) in a desert area approximately ten miles from Khobar. The camp area where my company bunked and took our meals was just downhill from the munitions storage area. Within the first weeks after getting in-country in February, I became aware that several of my men were becoming ill, with difficulty in breathing, runny eyes, and diarrhea. Several men were hospitalized. Because of suspicions that living and working full time in close proximity to the munitions storage area had something to do with these illnesses, I requested a change in the location of our camp area and recommended the establishment of rotating duty shifts to cover the security requirement. These recommendations were accepted. I also asked headquarters to conduct a survey of the site to see what was wrong. An environmental assessment was conducted and on May 15, 1991, I received a copy of a memorandum, which I ask be placed in the record, which stated that this site (ASP Quarry) "has now been identified as containing significant respiratory hazards, both in the form of toxic gases...and various airborne particulates." The memo, from a headquarters physician, made reference to a protective mask which had been found successful in filtering out particulates, and stated "[I]t is vital that a protective mask of the above type be made available to every soldier who will be on duty in A.S.P. Quarry..." Many of my men were alarmed by the issuance of these

masks, but we wore them while on security rotations. My request to my brigade commander for a copy of the environmental report received no response. (See copy of memo, to be placed in the record). I do not have personal knowledge of what we may have been exposed to at ASP Quarry, but in attending a very high level meeting at a later date I heard a conversation among high-ranking officers that indicated that unconventional, highly classified ordnance was among the ordnance stored there.

My company's experience in Saudi also included numerous warnings of SCUD launches. After many false alarms, my men had become more relaxed about the loud warnings, "SCUD launch". But we were less than a mile from the SCUD that killed 23 men; I was relatively lucky, I only sustained a concussion in seeking cover from the clearly visible incoming rocket. The injury led to total loss of hearing in one ear.

I am proud of my service in Saudi, and of the Bronze Star and Army Commendation Medal I received for that service. I am convinced, however, that something (other than my hearing loss) happened to me and to numbers of my men in the Persian Gulf. I began to have problems almost as soon as I returned to the States. I couldn't pinpoint a cause, but I had difficulty sleeping, difficulty in breathing, was constantly fatigued, had joint pain, memory loss, and stomach

problems. I had had none of these problems before serving in Saudi.

I have been a relatively high-achiever, and before my military service, I completed college studies earning a B.A. degree from the University of Maryland. I was unprepared, however, to deal with the health problems I experienced after returning from Saudi Arabia, and I regret that I turned to alcohol to mask the pain. (Only after serious family problems did I stop drinking, and have been active in AA since 1993). My health problems did not improve, and finally, with the establishment of the VA's Registry program several years later, I turned to the VA. I was evaluated extensively by the VA Medical Center in Washington, D.C., and later by Walter Reed Army Medical Center. These evaluations, which included extensive testing during a period of VA hospitalization, led to my being diagnosed as suffering from sleep apnea, fibromyalgia, degenerative joint disease, and PTSD.

I especially want to acknowledge that I have gotten a lot of help from the VA medical center's PTSD program, and I have very high regard for their clinical staff. They have helped me cope with what I'm going through. I continue to be under treatment from VA, and receive medication. My other medical problems still give me a lot of trouble, though. I have almost come to accept that if VA and Walter Reed have been unable to resolve

these problems, that they are not likely to get better, and I will have to learn to live with them.

As one who served in war for his country and, I believe, became sick as a result, I do expect that those who work to assist veterans will be empathetic, and give me some special consideration. Many VA clinicians and staff have done just that, and I do want to acknowledge that. For example, when I have had problems there, the VA's patient advocate at the Washington VA medical center has "jumped on it" and resolved them. But there have been frustrations.

If it is not possible to cure my health problems, I believe the Government should acknowledge that they are due to military service, and provide appropriate compensation benefits and vocational rehabilitation (because it is increasingly difficult with my joint pains to work at a job that requires me to stand all day). Unfortunately, I've had a lot of problem getting favorable action, or any action, on my claim for service-connection, which I first filed years ago. Even my hearing loss, which is documented in my military medical records in 1991, has yet to be adjudicated as service-connected.

While the many physicians that have treated or evaluated me have generally been concerned, a few seemed like they were just going through the motions. In one

particularly upsetting case, a psychologist at Walter Reade wrote a statement in my medical records to the effect that I might be faking symptoms. It was also unsettling to have to wait about four months to undergo VA testing for a severe sleep disorder. The negative experiences I have had as a patient - such as long waits to discuss my case with a physician, an error in my medication, and being billed in error for care that was supposed to be free -- may seem trivial, but after years of battling these health problems, even small issues become large.

In closing, let me say that I am testifying not just for myself, but for the many others who are also hurting. Although I am not the man I was when I left for Saudi Arabia, many of my troops are still looking to me to take care of them. I hope this Committee will help me help them.

Thank you.

DEPARTMENT OF THE ARMY
276th MILITARY POLICE COMPANY
APO NEW YORK 09616-5000

MPBN-AB-F

28 MAY 1991

MEMORANDUM THRU ~~Commander 400th Military Police Camp (PW)~~ 

FOR Commander 800th Military Police Brigade

SUBJECT: Environmental Report

1. On several occassion this command requested a copy of the results of the survey that was conducted by your staff.
2. An alpha roster of personnel assigned to this company was provided to be attached to the report. I was informed by your staff that the report has been completed and awaiting signature and I was to check back ~~on~~ that your staff would deliever the document.
3. Today, I was informed that the report has been packed away and that it would be forwarded to us after returning to CONUS.
4. This report is necessary for future reference regarding hazardous conditions that my personnel were exposed to while performing their daily duties. The conditions in which they worked may have long lasting effects on their health. Several members of this command have been hospitalized or placed on quarters for respirtory complication.
5. The report would serve as a reference document that we were linked to the conditions surveyed and highlighted in your report for future health problems that may arise and may facilitate the use of medical benefits and facilities.
6. POC will be the under sign at either Khobar Towers, Bldg 206, 4th Floor or 276th MP Co, ANS, Stop 23, Bldg 351, Washington, DC 20315-0351, comm 202-433-2475, Autovon 288-2437.



DEREK E DAVIS
CPT, MP
Commanding

DEPARTMENT OF THE ARMY
HEADQUARTERS, 400TH MILITARY POLICE CAMP (PW)
APO , NEW YORK 09616-5000

FD-ACC-G-MD

23 APRIL 1991

SUBJ: MAJOR JOHNSON AND MAJOR CORLEW, CONTRACTING

EFFECT: Acquisition Of Respiratory Protective Masks For 276TH MP

A.S.P. Quarry has now been identified as containing significant respiratory hazards, both in the form of toxic gases ("Smog") and various airborne particulates.

A recent trial of a commercial protective mask, designed to filter out particulates was successful. The mask was both comfortable and effective.

Continued use of this protective mask will block any harmful fumes by particulates as long as the mask is in place.

It is vital that a protective mask of the above type be made available to every soldier who will be on duty in A.S.P. Quarry, together with an ample supply of replacement filtering elements.



GILBERT H. FERRIS
LTC, MD
SURGEON

Rec'd 109 on 15 May 1991
over a month later

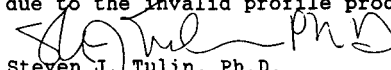
PSYCHOLOGICAL EVALUATION

DAVIS, DEREK

February 16, 1996

The patient is a 40 year old male who was referred for Phase II evaluation. His initial complaint was of chronic fatigue, muscle weakness, SOB, and vision problems, but he also noted that he had been diagnosed as having PTSD. He complained of sleep trouble, irritability, and depression. He noted that he has been in AA for a year, but drank approximately one pint of liquor per day from 1991-1994. The patient endorsed vague cognitive complaints. The patient left many items blank when the MMPI 2 was completed. When this was pointed out to him he behaved in a somewhat hostile manner.

Results of the MMPI 2 completed by the patient were invalid due to the extremely high number of items suggesting pathology which were endorsed by the patient. Similar profiles are obtained by patients attempting a "cry for help", or those exaggerating difficulties in order to obtain some form of compensation. Intentional feigning of difficulties cannot be ruled out in this case. The nature of possible actual Axis I or II pathology cannot be verified due to the invalid profile produced on the MMPI 2.

 Ph.D.
Steven J. Tulin, Ph.D.
Neuropsychologist

→ overt Bermanity
? "Faking"

TESTIMONY OF CARL E. WICKLINE
TO THE
HOUSE VETERANS' AFFAIRS COMMITTEE
PRESIDENTIAL ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES
ON
FEBRUARY 11, 1997

The issue of treatment and diagnosis of illnesses contracted by service members while serving in Operations Desert Shield and Desert Storm have raised a variety of pertinent problems within the Veterans Administration health care programs. The issue most urgently in need of attention is that of diagnosis and system wide treatment protocol. Second is that of compensation and continued long term treatment programs.

My own experiences within the Veterans Administration are an excellent example which support my previous statement. I was recently asked to summarize my dealings with the Veterans Administration concerning the treatment of a variety of unexplainable medical symptoms which became noticeable shortly after returning from the Gulf. Please bear in mind that the observation and subsequent conclusions which I have drawn contain many of my own opinions. They are, quite simply, my own opinions. I am not a medical professional by any means. I am, an educated man, a functioning member of society, taxpayer, voter business man and honorable discharge United States Marine. As such, it is not unreasonable to expect to be treated with the care and respect which I feel has been earned by the thousands of (sick?) veterans risked their lives and returned home after service in the Gulf War.

I would like to state up front that I understand the tremendous responsibility that is upon the Veterans Administration each day. I commend the dedicated group of medical professionals who apply themselves on a daily basis to the health care of veterans throughout the United States.

My first contact with the Veterans Administration came shortly after being discharged from service. In September 1993, I filed a claim which cited both military medical records and discharge physical as support for my application for disability benefits due to this "syndrome" which has been so hard to diagnose and treat. Symptoms at that time included chronic nausea and vomiting, severe headaches, chronic fatigue, sleep disorders, night sweats, memory/concentration problems, immune system breakdown, severe depression and uncontrollable mood swings.

My claim dated September 1993 was denied less than a year later. I subsequently filed a new claim dated March 1995. This claim is still "pending" a VA ratings board in Nashville, Tennessee. Initially the complaints of these symptoms were overlooked while I was referred to Mental Health for evaluation and treatment for depression. Several attempts were made to go through the outpatient clinic at the Lexington, Kentucky VA hospital. On each occasion I came in complaining of the same symptoms

with similar results each time. Attempts were made to alleviate the symptoms with medication. Most of these attempts were unsuccessful or temporary at best. Basic blood tests have been done but any actual research or in depth testing has been overlooked. Neurological workup was done with no conclusive results. At this time I was referred back to Mental Health.

It seems that I end up in the same place each time I attempt to contact the VA concerning my illness. Mental Health must be the dead end of all cases which the VA has no knowledge or interest in treating. I have been prescribed three different antidepressants and a seizure medication; none of which have had any effect other than to increase fatigue and gastrointestinal problems. I must say that the Mental Health unit in Lexington, Kentucky has some wonderfully dedicated doctors who provided some much needed counseling. However, they were no help in the treatment of the mysterious symptoms of which I have suffered for nearly six years now.

My most recent visit to the VA was December 16, 1996 in Oklahoma City, Oklahoma. At this meeting I provided the doctor with a complete list of symptoms, exposure listings, test results from several professional medical laboratories, as well as doctors diagnosis, I also specifically request treatment for Gulf War Syndrome. I was told by this doctor that he was not interested in seeing any of the documentation which I had provided. I was also told that research and treatment for Gulf War Syndrome was not available to me at this time. I was told that he did not have time to look at my paperwork and that I was obviously suffering from depression and possibly hypertension. After which I was prescribed an anti-depressant and a stomach medication. A return appointment and basic blood work have been scheduled for February 1997.

I would have considered this episode to have been, at best, a simple oversight had I not encountered similar incidents on several occasions throughout my dealings with the VA healthcare system. Once again I find myself in the same spot in which I always seem to find myself. The issues have once again been side-stepped and I still suffer from the same symptoms for which I have seen no honest attempts toward diagnosis or treatment.

Thank you for your time and attention to this matter. I hope to see this situation resolved in the near future; however, I fear that mine is not an isolated case and the wheels turn slowly.



NATIONAL MILITARY AND VETERANS ALLIANCE

Telephone: (703) 750-2568 Fax: (301) 899-8136

STATEMENT OF

LARRY D. RHEA

COMMAND MASTER CHIEF, U.S. NAVY (RETIRED)

DEPUTY DIRECTOR OF LEGISLATIVE AFFAIRS

NON COMMISSIONED OFFICERS ASSOCIATION OF THE USA

FOR THE

THE NATIONAL MILITARY AND VETERANS ALLIANCE

TO THE

COMMITTEE ON VETERANS AFFAIRS

UNITED STATES HOUSE OF REPRESENTATIVES

ON

THE PRESIDENTIAL ADVISORY COMMITTEE

ON GULF WAR VETERANS' ILLNESSES

FEBRUARY 11, 1997

Participating Organizations: Air Force Sergeants Association ♦ American Retirees Association ♦ Korean War Veterans Association
♦ Military Order of the World Wars ♦ National Association for Uniformed Services ♦ Naval Enlisted Reserve Association
♦ Naval Reserve Association ♦ Non Commissioned Officers Association ♦ Reserve Officers Association ♦ The Tragedy Assistance
Program for Survivors ♦ Veterans of Foreign Wars

The National Military and Veterans Alliance sincerely appreciates the opportunity to testify today on this important issue. This hearing, following the report of the Presidential Advisory Committee and other recent revelations, is especially timely. The Alliance salutes the Distinguished Chairman for scheduling and holding a full-committee hearing on this important, perplexing and highly emotional issue.

This testimony has been endorsed by and is presented on behalf of the National Military and Veterans Alliance (NMVA), hereafter referred to as The Alliance. The Alliance is comprised of nationally prominent military and veterans organizations who collectively represent over 3 million members of the seven uniformed services - officer, enlisted, active-duty, National Guard and Reserve, retired and veterans plus their families and survivors.

The Alliance organizations endorsing this testimony and for whom it is being presented are: American Military Retirees Association; American Retirees Association; Air Force Sergeants Association; Korean War Veterans Association; Military Order of the Purple Heart; National Association for the Uniformed Services; Naval Enlisted Reserve Association; Naval Reserve Association; Non Commissioned Officers Association of the USA; and the Veterans of Foreign Wars.

The Alliance wishes to begin its testimony with a restatement of the position that The Alliance has held since the time it became obvious that many Persian Gulf War veterans had serious illnesses.

In those earlier days, it was painfully apparent that significant numbers of Persian Gulf War veterans were experiencing conditions and symptoms that suggested a possible link to their service in the Persian Gulf Theater. The Alliance took the position that aggressive scientific research must be undertaken. Additionally, The Alliance advocated and strongly supported the development of case assessment protocols, case definitions, and the outreach and registry programs in addition to the scientific and medical research which was crucial to finding answers. Throughout, The Alliance has steadfastly maintained that reliable scientific research

and evidence to either support or refute the cause and effect relationship must eventually decide the final outcome on Persian Gulf Syndrome (PGS).

In the beginning, The Alliance certainly knew that answers to the many complex questions would not be immediately available. Pending the accumulation of sufficient scientific data and answers to the multitude of questions, The Alliance advocated that the "benefit of the doubt" be given to the veteran. Hence, many organizations participating in The Alliance lobbied for and supported legislative initiatives to provide medical care and disability compensation to PGS veterans. Those organizations believed then, and The Alliance believes today, that when an element of doubt exists, the decision should always favor the veteran.

Most of the efforts undertaken thusfar have resulted from the initiatives of Congress through this Committee and the Veterans Affairs Committees. In the Alliance's view, Congress has done a remarkable job in keeping attention on the issue properly focused. The Alliance also believes that Congress did the proper thing by extending medical care and disability compensation to PGS veterans. The Alliance is deeply appreciative for what the Distinguished Chairman, the Ranking Member and, indeed all Members of the Committee have done and are continuing to do. It is also crystal clear to The Alliance that your continued attention will be necessary.

Mr. Chairman, the Nation is now more than five years into the PGS issue. In some respects, we are not any closer to the sought after answers than when PGS first manifested itself. In other respects, and thankfully so, considerable progress has been made. The Alliance is referring to the unity of purpose which now seems to exist. It appears to The Alliance that DOD, VA, the medical community and the Nation have finally coalesced around PGS and the veterans so affected. That in itself is marked progress in our estimation.

The Alliance organizations were briefed on the Final Report of the Presidential Advisory Committee on Gulf War Veterans' Illnesses and each was provided a copy of the report. The Alliance commends the Advisory Committee members for their sixteen month effort and

endorses the continuation of their work as the President has directed. Generally speaking, The Alliance is satisfied with the Advisory Committee's report and recommendations. In the opinion of The Alliance, the report is balanced and insightful. However, The Alliance believes it is important to comment at this hearing on two areas of the report.

The Advisory Committee recommended that further investigation be conducted into possible exposure to chemical or biological agents. The Alliance concurs with this recommendation and the Advisory Committee's desire that it be conducted by, or at least overseen by, a group independent of the Defense Department. In agreeing with an independent effort on the possible exposure to chemical or biological agents, The Alliance is by no means casting any aspersions on the Department of Defense. At the same time though, The Alliance cannot ignore or downplay the high level of distrust which exists among many PGS veterans. Independent investigation or oversight is probably necessary, if for no other reason than as a step toward restoring the lost trust.

The Alliance's second comment relative to the Advisory Committee's report pertains to stress as a causal factor for PGS which the report described as a likely contributor to a broad array of illnesses. Clearly, the theory should be explored as the research and investigation continues. We must acknowledge now though that stress is an ever present commodity of military service that is not restricted just to periods of conflict. Mr. Chairman, The Alliance urges that caution be exercised as the theory on stress and PGS is explored. In the efforts to find answers and to find them as quickly as possible, let's not yield to the temptation to use the stress theory as a broad umbrella to mask or divert attention from other potential causal factors. While stress may very well be revealed as a factor, the Alliance urges caution to not make the immediate, tempting leap to broadly classify these illnesses as purely psychological.

One day after the Presidential Advisory Committee released its report, independent research was released that appears in conflict with the committee's results. The Alliance recognizes that the results of these newly released Independent studies are preliminary and limited.

Those results though, coming the day following the Advisory Committee's Report, illustrate precisely where we are in this process of searching for answers. It is obvious that opinions among the scientific and medical communities vary greatly nearly five years after the search for answers started. The wise course of action at this point, in The Alliance's view, would be to not rule out anything or a combination of things as a causal factor or factors.

Therefore, The Alliance believes this Committee should continue to emphasize research and study in all possible directions - chemical and biological agent exposure; low-level exposure to certain nerve agents and pesticides; the effects of the anti-nerve agent Pyriostigmine bromide and other chemicals; as well as the long-term health effects of stress. Doctor Kizer has indicated a willingness to consult with private-sector doctors with experience in toxic substances and The Alliance urges him to do so. Clearly, a lot of work remains to be done. The Alliance believes we are obligated to stay the course not only for PGS veterans but also for the veterans of future wars.

Earlier in this testimony, The Alliance commended this Committee and Congress for the resolve demonstrated on this perplexing issue. It is also appropriate for The Alliance to recognize and commend the Department of Veterans Affairs, Secretary Jesse Brown and Doctor Ken Kizer for their resolute efforts.

The Alliance applauds Secretary Brown's decision to re-open an estimated 11,000 previously denied cases for another look and reconsideration of the prior decisions in those cases. The Alliance fully supports Secretary Brown's decision and the Department of Veterans Affairs in this undertaking.

The Alliance is also pleased that the Persian Gulf compensation presumptive period is being reevaluated. At the time the two-year presumptive period was set, it was done in a highly arbitrary manner. Therefore, The Alliance is extremely pleased that consideration is being given to extending the presumptive period. The Alliance looks forward to Secretary Brown's recommendation in this regard.

In closing, The Alliance reaffirms to the Committee the position as stated at the beginning of this testimony. Aggressive research and epidemiological studies must be continued in all possible directions. Caution must be exercised to not rule out any possibilities at this point. Medical care and disability compensation for these PGS veterans must also continue. The Alliance believes that we must rely on the scientific community to provide the answers and ultimately determine the final outcome. The Alliance urges the Committee to stay the course until scientific data are sufficient and irrefutable.

Thank you.

WRITTEN COMMITTEE QUESTIONS AND THEIR RESPONSES

**POST-HEARING QUESTIONS
CONCERNING THE FEBRUARY 11, 1997
HEARING ON PERSIAN GULF WAR VETERANS' ILLNESSES**

**FOR THOMAS L. GARTHWAITE, M.D.
DEPUTY UNDER SECRETARY FOR HEALTH
DEPARTMENT OF VETERANS AFFAIRS**

**SUBMITTED BY THE HONORABLE BOB STUMP
CHAIRMAN, COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES**

Question 1: With respect to what you characterized in your testimony as a "well designed and comprehensive" health care program, is your testimony simply describing the department's diagnostic efforts (i.e., its Registry and Referral Center "programs") or a specific treatment "program" or "programs" as well?

Answer: This testimony referred to the diagnostic and treatment aspects of our comprehensive approach to VA's Persian Gulf programs. The first component of our Gulf War response was the establishment of a health care program, the VA Persian Gulf Registry health examination program. The Registry was developed in 1991 and implemented in 1992. VA provides Persian Gulf Registry Phase I health examinations and follow-up treatment at its medical facilities nationwide, and Phase II evaluations for those Persian Gulf veterans with difficult to diagnose problems.

Persian Gulf veterans with health problems that may be related to an exposure to a toxic substance or environmental hazard during active duty service in the Gulf War, have special eligibility for VA hospital care and outpatient medical services. In addition, VA has established Referral Centers for those veterans whose medical conditions are complex and have eluded diagnosis at their local VA medical facility. VA has also established a Depleted Uranium Medical Surveillance program at the Baltimore VA Medical Center.

Persian Gulf veterans' illnesses span the entire range of medical diagnoses. No single diagnostic category predominates, however, the full spectrum of appropriate treatments are available within the VA at medical facilities and Vet Centers nationwide. No unique treatments have been proven effective for Persian Gulf veterans' illnesses and therefore no specialized "treatment" programs have been established.

Question 2: Is there a specific, systemwide Persian Gulf War veterans' treatment program or specific national guideline(s) on the care or coordination of care of Persian Gulf War veterans, as distinct from the registry program, eligibility criteria, and general programs and directives and provision of VA health care services. If so, please furnish a copy of the applicable publication(s) regarding such program(s) or directive(s), as well as the specific accountability measures for insuring appropriate outcomes.

Answer: Refer to the following attachment: VA/VHA Manual M-10, Environmental Agents Service, Part III, Persian Gulf Program. Manual Chapters 1-5 set forth the clinical and administrative policies and procedures related to the establishment and maintenance of VHA's Persian Gulf Registry programs. Page 2-2 (2.04a) gives further guidance concerning assignment of Persian Gulf War veterans needing follow-up care to a primary care team.

Question 3: Please provide a copy of the VHA-established quality monitors and performance standards applicable to the Registry programs.

Answer: Refer to the following attachments: 1) VHA Directive 10-95-114, Persian Gulf Registry Health Examination Program, Quality Management/Self Assessment Monitor (November 1995), 2) VHA Directive 96-051, Veterans Health Administration Special Emphasis Programs, Page A-10, (August 1996), 3) VHA Directive 97-008, VHA's Service Evaluation and Action Team (February 1997), 4) Under Secretary for Health's Information Letter, VHA's Service Evaluation and Action Team (SEAT) [March 1997]; and 5) VA/VHA Manual M-10, Environmental Agents Service, Part III, Persian Gulf Program.

Question 4: Your testimony with respect to the imperfections and inconsistencies in VA health care programs for Persian Gulf veterans appeared to acknowledge problems in delivery of health care services other than in the registry program itself. To the extent that your testimony addressed treatment-related (vs. Registry related) problems, however, the only specific action or initiative identified in your testimony was establishment of a "SEAT" team in each network to "collect data for quality improvement". Are there any other initiatives in place or underway to address PGW treatment issues? If so, please discuss.

Answer: VA's SEAT program is an addition to the established quality indicators and performance standards for the Registry examinations that are already in place, and the VA medical center quality improvement programs. Specifications for these existing Registry program requirements are included in VA/VHA Manual M-10, and the VHA Directives which we listed in response to Questions No. 2 & 3 above. The SEATs will provide us with a mechanism to continually assess opportunities to enhance the effectiveness of VA clinical programs and respond to veterans' concerns.

In addition to these efforts, VA seeks to enhance the consistency and quality of care for Persian Gulf veterans, and has implemented several initiatives designed to improve medical care. We have utilized nationwide conference calls, satellite video-teleconferences, mailings, and annual on-site continuing medical education (CME) conferences to keep our health care providers well-informed on Persian Gulf-related clinical and research issues. These efforts have been successful in educating our Registry physicians and staff, and we will continue to keep them up-to-date on the latest developments. However, we want all VA health care providers to have a working understanding of Gulf War exposures and health issues so they will be able to address the health concerns of their Persian Gulf patients. In order to meet this challenge and improve our programs, VHA is developing a self-study CME program for physicians which will supplement our current educational endeavors. VA's customer feedback center is developing patient satisfaction surveys which will target Persian Gulf veterans. The center has surveyed over 200,000 veterans overall and their data is a critical part of our expanding performance measurement system. The results of these assessments will guide additional clinical and research program changes, as well as our future educational efforts.

Question 5: Is the focus of the SEAT teams' evaluation activities limited in focus to PGW-treatment issues, or VA care generally?

Answer: The SEATs will be piloted initially with health care provided to Persian Gulf veterans. This would include Registry examinations, Referral Center evaluations, and outpatient and inpatient care delivered within the VA health care system. If successful, the evaluation activities will be expanded to encompass other special program areas in the future.

Question 6: Please provide any published directives and guidelines on the SEAT teams' operations. Are its members to be devoted full-time to evaluation and data collection, or are these collateral duties for some or all of its members?

Answer: Refer to the attachment provided in response to Question No. 3 above: VHA Directive 97-008, VHA's Service Evaluation and Action Team (February 1997). The membership of the SEAT and their duties and responsibilities are outlined under No. 3 of this Directive. Members assume their duties as SEAT participants as collateral duties.

List of Attachments

- VHA Directive 10-95-114, Persian Gulf Registry Health Examination Program, Quality Management/Self Assessment Monitor (November 1995).
- VHA Directive 96-051, Veterans Health Administration Special Emphasis Programs, Page A-10, (August 1996).
- VHA Directive 97-008, VHA's Service Evaluation and Action Team (February 1997).
- Under Secretary for Health's Information Letter, VHA's Service Evaluation and Action Team (SEAT) [March 1997].
- VA/VHA Manual M-10, Environmental Agents Service, Part III, Persian Gulf Program.
- VHA Directive 96-073, Revisions in Authorities for Provision of Priority Health Care for Certain Veterans Exposed to Specified Toxic Substances (December 2, 1996).
- VHA Directive 96-064, Public Law 104-262, VA Health-Care Eligibility Rules Effective October 9, 1996 (November 8, 1996).

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA Directive 10-95-114

November 21, 1995

**PERSIAN GULF REGISTRY HEALTH EXAMINATION PROGRAM
QUALITY MANAGEMENT/SELF ASSESSMENT MONITOR (RCS 10-0860)**

1. **PURPOSE:** The purpose of this Veterans Health Administration (VHA) Directive is to provide procedures on use of VA Form 10-9009C-1, Persian Gulf Registry Health Examination Program - Quality Management/ Self Assessment Monitor (Att.). This instrument has been developed as a quality management tool for conducting reviews of Persian Gulf War veteran's medical records. It is to be used by VA medical centers to assess and monitor the appropriateness of medical care being provided in accordance with the Protocol for Conducting the Physical Examination and Ordering Diagnostic Studies (M-10, Pt. III, Ch. 2, App. 2B).

2. **BACKGROUND:** Approximately 697,000 American servicemen and servicewomen were involved in the Persian Gulf War. A number of these troops may have been exposed to environmental hazards, and/or possible diseases endemic to the Southwest Asia theater of operations.

a. Public Law 102-585, enacted in November 1992, authorized establishment of the VA's Persian Gulf War Veterans Health Registry. That law authorized the VA to provide a comprehensive medical examination, including any diagnostic testing, to evaluate the veteran's health status.

b. An Office of Inspector General (OIG) Report, "An Oversight Evaluation of the Department of Veterans Affairs' Response to Health Care Issues Relating to Military Service in the Persian Gulf War" (5HI-A28-011; December 29, 1994), recommended that VA facilities assure that all Persian Gulf War veterans have been afforded appropriate medical care by conducting peer reviews of a statistically valid sample of Gulf veteran's medical records.

3. **POLICY:** VA is committed to providing high quality medical care to veterans, and to ensure that this goal is met for Persian Gulf War veterans, appropriate mechanisms must be put in place to address their special needs and health problems. We also must monitor the effectiveness of the services provided to them.

4. **ACTION**

a. Each VA medical center will use the Persian Gulf Registry Health Examination Program - Quality Management/Self Assessment Monitor to review, at least, a 10% sample of all Persian Gulf Registry physical examinations conducted to date.

b. The first such review will be conducted by each VA medical center within a time-frame that ensures that results are provided to the Environmental Agents Program (131), VHA Headquarters, no later than January 31, 1996. Subsequent reviews should be conducted on an annual basis thereafter, with results submitted to (131) by October 1 of each year.

c. Results of the review should be recorded on VA Form 10-9009C-2, Summary Analysis of Self Assessment Monitor Results (Att. B) for submission at the following address:

Director, Environmental Agents Program (131)
VHA Headquarters
810 Vermont Ave., N.W.
Washington, DC 20420
FAX 202-565-7572

THIS VHA DIRECTIVE EXPIRES NOVEMBER 21, 2000

VHA DIRECTIVE 10-95-114
November 21, 1995

d. Questions may be referred to Director, Environmental Agents Program (131), at 202-565-4183, or Environmental Agents Program staff at 202-565-4548.

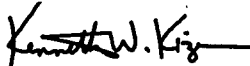
5. REFERENCES

a. M-10, Part III, Chapters 1-4.

b. Office of Inspector General (OIG) Report, "An Oversight Evaluation of the Department of Veterans Affairs' Response to Health Care Issues Relating to Military Service in the Persian Gulf War" (5HI-A28-011; December 29, 1994).

6. FOLLOW-UP RESPONSIBILITY: Director, Environmental Agents Program (131), is responsible for the content of this Directive.

7. RESCISSIONS: None. This VHA Directive will expire November 21, 2000.



Kenneth W. Kizer, M.D., M.P.H.
 Under Secretary for Health

Attachments

DISTRIBUTION: CO: E-mailed 11/24/95
 FLD: RD, MA, DO, OC, OCRO, and 200 - FAX 11/24/95
 EX: Boxes 104, 88, 63, 60, 54, 52, 47 and 44 - FAX 11/24/95

Attachment A

VHA DIRECTIVE 10-95-114
November 21, 1995

Persian Gulf Registry Health Examination Quality Management/Self Assessment Monitor

FACILITY LOCATION (City & State): _____

FACILITY NUMBER: _____

PERSIAN GULF COORDINATOR: _____

VETERANS REGISTRY PHYSICIAN(S): _____

PATIENT NAME (Last/First/MI): _____

PATIENT SSN:

 -

 -

A. Required Components of the Registry Examination

Code Sheet in CHR (Consolidated Health Record):

Yes No

 1. Thorough History and Physical Examination
 in CHR, such as completion of an SF88.

Yes No

2. Women Persian Gulf Veterans:

Yes No

Refused

a. Breast Exam

Yes No

Refused

b. Gynecology Exam

3. Laboratory Results in CHR:

Yes No

a. CBC

Yes No

b. Chemistries

VHA DIRECTIVE 10-95-114
November 21, 1995

c. Urinalysis

Yes No

d. Chest X-ray

Yes No

4. A follow-up visit is recorded?

Yes No

NA

5. Follow-up letter, containing exam results
and recommendations is in CHR (or mailed)?

Yes No

6. Additional Diagnostic Work-up for Selected
Symptoms:

The following examinations were ordered
by the physician, if the veteran complained
of:

a. Persistent Diarrhea:

i. Rectal Exam

Yes No

Refused

ii. Stool guaiac

Yes No

iii. Stool WBC

Yes No

iv. Stool for ova/parasites

Yes No

v. GI consult

Yes	No
☐	☐

b. Memory Loss

i. Mini-Mental Status Exam or other bedside memory test

Yes	No
☐	☐

ii. Additional Labs:

Thyroid Functions

Yes	No
☐	☐

VDRL (RPR)

Yes	No
☐	☐

812

Yes	No
☐	☐

Other (Neurology consult, CT/MRI)

Yes	No
☐	☐

c. Shortness of Breath or Chronic Cough

i. Lung Exam Recorded

Yes	No
☐	☐

ii. Pulmonary Function Test

Yes	No
☐	☐

iii. Smoking History

Yes	No
☐	☐

VHA DIRECTIVE 10-95-114
November 21, 1995

B. Follow-up Appointments

1. If the veteran was symptomatic at the time of completion of the Registry exam was a follow-up examination scheduled?

Yes No

2. Has the veteran been assigned to a primary care team?

Yes No

Attachment B

VHA DIRECTIVE 10-95-114
November 21, 1995

SUMMARY ANALYSIS OF SELF-ASSESSMENT MONITOR RESULTS

VAMC/OPC:

[illegible]

CITY:

[illegible]

STATE:

VAMC/OPC NUMBER:

VISN SITE NUMBER:

PERSON COMPLETING SURVEY:

LAST NAME:

[illegible]

FIRST NAME:

TELEPHONE NUMBER:

Area Code _____

Extension

A. BACKGROUND:

1) NUMBER OF PERSIAN GULF VETERANS WHO RECEIVED REGISTRY EXAMINATIONS IN 19 ____ (STATE YEAR).

$$N =$$

2) SAMPLE PERCENTAGE =

 %

% Male

% Female

B. STANDARD REGISTRY EXAM:

1) NUMBER OF CHARTS THAT CONTAINED CODE SHEETS.

$$N =$$

NON-COMPLIANCE =

 %

VHA DIRECTIVE 10-95-114
November 21, 1995

2) NUMBER OF CHARTS THAT CONTAINED A HISTORY AND PHYSICAL (SF88).

NON-COMPLIANCE = %

N =

3) NUMBER OF CHARTS THAT CONTAINED CBC TEST RESULTS.

NON-COMPLIANCE = %

N =

4) NUMBER OF CHARTS THAT CONTAINED CHEMISTRIES.

NON-COMPLIANCE = %

N =

5) NUMBER OF CHARTS THAT CONTAINED URINALYSIS.

NON-COMPLIANCE = %

N =

6) NUMBER OF CHARTS THAT CONTAINED CHEST X-RAY.

NON-COMPLIANCE = %

N =

7) NUMBER OF CHARTS THAT RECORDED A FOLLOW-UP VISIT.

NON-COMPLIANCE = %

N =

8) NUMBER OF CHARTS THAT CONTAINED A FOLLOW-UP LETTER.

NON-COMPLIANCE = %

N =

2. WORK-UP FOR COMMON COMPLAINTS:

9) NUMBER OF CHARTS THAT CONTAINED SYMPTOM-SPECIFIC EXAMINATIONS IF PATIENT COMPLAINED OF PERSISTENT DIARRHEA.

NON-COMPLIANCE = %

N =

10) NUMBER OF CHARTS THAT CONTAINED SYMPTOM-SPECIFIC EXAMINATIONS IF PATIENT COMPLAINED OF MEMORY LOSS.

N =

NON-COMPLIANCE =

 %

11) NUMBER OF CHARTS THAT CONTAINED SYMPTOM-SPECIFIC EXAMINATIONS IF PATIENT COMPLAINED OF SHORTNESS OF BREATH/CHRONIC COUGH.

N =

NON-COMPLIANCE =

 %

12) NUMBER OF CHARTS THAT SHOWED A FOLLOW-UP APPOINTMENT HAD BEEN SCHEDULED.

N =

NON-COMPLIANCE =

 %

D. PRIMARY CARE TEAM ASSIGNMENT:

13) NUMBER OF CHARTS THAT SHOWED PATIENT HAD BEEN ASSIGNED TO A PRIMARY CARE TEAM.

N =

NON-COMPLIANCE =

 %

E. WOMEN VETERANS:

14) NUMBER OF FEMALE PATIENT CHARTS THAT SHOWED COMPLETION OF BREAST EXAMINATION.

N =

NON-COMPLIANCE =

 %

15) NUMBER OF FEMALE PATIENT CHARTS THAT SHOWED COMPLETION OF NEOLOGY EXAMINATION.

N =

NON-COMPLIANCE =

 %

ATTACHMENT A**BLIND REHABILITATION SERVICE**

The mission of the Blind Rehabilitation Service is to improve the quality of life for blinded veterans by assisting them to develop the skills and capabilities needed for the attainment of personal independence and emotional stability. This is accomplished through identification of visually impaired veterans, provision of comprehensive inpatient and outpatient rehabilitation services, education of blinded veterans and their families, and research.

Population Measures

1. Blinded veterans demonstrate post rehabilitation improvement in functional status 6 months after discharge from a comprehensive VA blind rehabilitation program.
GOAL: 80%
2. Percentage of blinded veterans who receive VA blind rehabilitation outpatient services pre- and-post inpatient rehabilitation will realize shortened length of stay in the VA inpatient Blind Rehabilitation Program.
GOAL: 100%
3. Blinded veterans identified by a Visual Impairment Services Team (VIST) coordinator as needing blind rehabilitation will have access to a comprehensive inpatient blind rehabilitation program within 6 months.
GOAL: 100%
4. Percentage of fully or highly satisfied patients on National Blind Rehabilitation Service Customer Satisfaction Questionnaire.
GOAL: 85%

Program Measures

1. The number of blinded veterans on VIST rolls reflects the incidence of blindness of eligible blinded veterans in the VISN veteran population.
2. Percentage of eligible blinded veterans scheduled for evaluation for inpatient blind rehabilitation treatment within 30 days of identification.
GOAL: 100%
3. Percentage of blinded veterans on VIST rolls offered an annual review, which includes a yearly physical and eye exam, benefits review and blind rehabilitation evaluation.
GOAL: 100%
4. Percentage of veterans on VIST rolls satisfied with VIST services.
GOAL: 95%

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5. Percentage of veterans on Blind Rehabilitation Outpatient Specialist (BROS) rolls satisfied with BROS services.
GOAL: 95%
6. Percentage of blinded veterans receiving recommended prosthetics equipment within 30 days of discharge from BRC Program.
GOAL: 95%

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GERIATRICS AND LONG-TERM CARE PROGRAM

HOME-BASED PRIMARY CARE (HBPC)

The mission of the Geriatrics and Long-Term Care program is to provide health care and related support services for aged and other veterans requiring long-term care. This is accomplished through identifying needs and determining the setting most conducive to meeting these needs, while maintaining functional independence. Services are offered through a number of programs including Home Based Primary Care (formerly known as Hospital-Based Home Care); VA, Community, and State Nursing Home Care; Community-Based Long-Term Care; Geriatric Research, Education and Clinical Centers (GRECC); Geriatric Evaluation and Management Programs (GEMs); and State Home Construction and Per Diem Grants.

The mission of the Home-Based Primary Care (HBPC) program is to provide primary care, delivered by an interdisciplinary team of VA staff to homebound (often bedbound) patients for whom return to an outpatient clinic is not practical.

Population Measures

1. Patient satisfaction with HBPC.
GOAL: 95%
2. Initial contacts with the HBPC patient are made within 2 working days from the time of hospital discharge.
GOAL: 100%

Program Measures

1. HBPC programs are coordinated with the fee-basis or Medicare referral and/or home health aide services.
GOAL: 50%
2. Establish methodology for unit cost comparison of HBPC primary care versus alternative methods of such care.
GOAL: Establish baseline

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GERIATRICS AND LONG-TERM CARE PROGRAM

VA, COMMUNITY, AND STATE NURSING HOME CARE

The mission of the Geriatrics and Long-Term Care program is to provide health care and related support services for aged and other veterans requiring long-term care. This is accomplished through identifying needs and determining the setting most conducive to meeting these needs, while maintaining functional independence. Services are offered through a number of programs including Home Based Primary Care (formerly known as Hospital-Based Home Care); VA, Community, and State Nursing Home Care; Community-Based Long-Term Care; Geriatric Research, Education and Clinical Centers (GRECC); Geriatric Evaluation and Management Programs (GEMs); and State Home Construction and Per Diem Grants.

VA's nursing home care mission is to meet a portion of veteran demand for nursing home care through the VA operated Nursing Home Care Units, Community (Contract) Nursing Homes, and State Home Nursing Homes.

Population Measures

1. Patient and family satisfaction with nursing home care.
GOAL: 95%
2. Percentage of older (65+) veterans who use VA health care and receive nursing home care through VA-sponsored program (VA-operated, community, state home).
GOAL: 8%
3. Percentage of Nursing Home patients returned to hospital (Absent-Sick-In-Hospital).
GOAL: 15%
4. In VA Nursing Home Care Units, the percent increase in number of patients with high complexity Resource Utilization Group scores.
GOAL: 5%

Program Measures

1. The number of Multi-State Contract initiatives executed.
GOAL: 6
2. Percent of the CNH budget expended through Multi-State Initiated (M-SCI) contracting.
GOAL: 10%
3. Percent of patients with a Patient Assessment Instrument (PAI) completed for CNH placements.
GOAL: 50%

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GERIATRICS AND LONG-TERM CARE PROGRAM**COMMUNITY BASED LONG-TERM CARE**

The mission of the Geriatrics and Long-Term Care program is to provide health care and related support services for aged and other veterans requiring long-term care. This is accomplished through identifying needs and determining the setting most conducive to meeting these needs, while maintaining functional independence. Services are offered through a number of programs including Home Based Primary Care (formerly known as Hospital-Based Home Care); VA, Community, and State Nursing Home Care; Community-Based Long-Term Care (CBLTC); Geriatric Research, Education and Clinical Centers (GRECC); Geriatric Evaluation and Management Programs (GEMs); and State Home Construction and Per Diem Grants.

The mission of Community-Based Long-Term Care Programs is to provide contract adult-day health care and homemaker/home health aid services to veterans who are at a nursing home level of need.

Population Measures

The amount of funds expended for CBLTC expressed as percentage of the community nursing home budget.

GOAL: 5%

Program Measures

1. CNH funds are expended on the CNH Program or alternative community-based long-term care services (CBLTC).

GOAL: 100%

2. Percent increase in VA facilities participating in CBLTC (The baseline is 110 facilities).

GOAL: 20%

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GERIATRICS AND LONG-TERM CARE PROGRAM

GERIATRIC RESEARCH, EDUCATION AND CLINICAL CENTERS (GRECCs)

The mission of the Geriatrics and Long-Term Care program is to provide health care and related support services for aged and other veterans requiring long-term care. This is accomplished through identifying needs and determining the setting most conducive to meeting these needs, while maintaining functional independence. Services are offered through a number of programs including Home Based Primary Care (formerly known as Hospital-Based Home Care); VA, Community, and State Nursing Home Care; Community-Based Long-Term Care; Geriatric Research, Education and Clinical Centers (GRECC); Geriatric Evaluation and Management Programs (GEMs); and State Home Construction and Per Diem Grants.

The mission of the GRECC Program is to improve services that are maximally effective and appropriate in meeting the medical, psychological and social needs of older veterans, through:

1. Geriatric and gerontological research;
2. Training of health personnel and trainees in the provision of health care to older individuals; and
3. Development and evaluation of improved models of clinical services.

Population Measures

Data on effectiveness of GRECC clinical demonstration projects in improving patient outcomes is reported annually with recommendations for replication at other VA sites, as indicated by the data.

GOAL: 100%

Program Measures

Research:

1. The number of scientific papers authored/ co-authored each year by each GRECC research investigator (primary investigator or co-investigator on an active research project) in peer-reviewed journals (List Journals).
GOAL: ≥ 1
2. Percent of publications in peer reviewed journals by GRECC core staff listing their VA affiliation.
GOAL: 100%

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Education and Training:

3. Number and percent of GRECC host facility clinical staff (includes physicians and all associated health staff) who are offered education/training in caring for elderly veterans by the GRECC.
GOAL: ->95%
4. Number of clinical staff at other VA facilities who receive education/training in caring for elderly veterans in the GRECC.
GOAL: Establish baseline in 1st year
5. Percent of geriatric fellows (PGY 4 and 5 residents) and VA funded associated health trainees in geriatrics (e.g. advanced geriatric nurse practitioners, geriatric pharmacy residents, geropsychology postdoctoral fellows) who received a substantial portion of their specialized geriatric training from the GRECC and are practicing geriatrics/gerontology or have academic appointments involving geriatrics/gerontology 2 years after completion of training.
GOAL: Establish baseline
6. Number of ongoing clinical demonstration projects at each GRECC which annually evaluate and report on the project's effectiveness in delivering improved clinical services to the elderly.
GOAL: >=1

Consultation and Outreach

7. Number of improvements each year in geriatric research, education or clinical activity at each GRECC host facility as a result of GRECC consultation.
GOAL: >=1
8. Number of improvements each year in geriatric research, education or clinical activity at other VAMCs as a result of consultation/outreach from the GRECC.
GOAL: >=1

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GERIATRICS AND LONG-TERM CARE PROGRAM

GERIATRICS EVALUATION AND MANAGEMENT (GEM)

The mission of the Geriatrics and Long-Term Care program is to provide health care and related support services for aged and other veterans requiring long-term care. This is accomplished through identifying needs and determining the setting most conducive to meeting these needs, while maintaining functional independence. Services are offered through a number of programs including Home Based Primary Care (formerly known as Hospital-Based Home Care); VA, Community, and State Nursing Home Care; Community-Based Long-Term Care; Geriatric Research, Education and Clinical Centers (GRECC); Geriatric Evaluation and Management Programs (GEMs); and State Home Construction and Per Diem Grants.

The mission of the GEM Program is to enhance the quality of life for selected elderly veterans, by improving clinical care, diagnosis, polypharmacy, discharge planning, functional status, and utilization. The GEM Program also provides a site for geriatric education and clinical research.

Population Measures

Percentage of frail elderly veterans who received VA GEM services and were discharged to home or community residential setting.

GOAL: 65%

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GERIATRICS AND LONG-TERM CARE PROGRAM**STATE HOME PER DIEM GRANTS**

The mission of the Geriatrics and Long-Term Care program is to provide health care and related support services for aged and other veterans requiring long-term care. This is accomplished through identifying needs and determining the setting most conducive to meeting these needs, while maintaining functional independence. Services are offered through a number of programs including Home Based Primary Care (formerly known as Hospital-Based Home Care); VA, Community, and State Nursing Home Care; Community-Based Long-Term Care; Geriatric Research, Education and Clinical Centers (GRECC); Geriatric Evaluation and Management Programs (GEMs); and State Home Construction and Per Diem Grants.

The State Home Per Diem Grant Program assists States in the cost of care provided veterans in State homes recognized by VA. The assistance to States through this grant program promotes Federal-State sharing in meeting part of the veteran demand for institutional long-term care.

Population Measures

1. Compliance with the quality of care standards for the level(s) of care provided by the state home (domiciliary, nursing home, hospital) is documented and reported by the VA facility of jurisdiction annually and as indicated.

GOAL: 100%

2. Correction of quality of care and/or life safety deficiencies by the state home according to specified timeframe is documented and reported by the VA facility of jurisdiction.

GOAL: 100%

Program Measures

1. Analysis of current per diem rates and recommendations for increases in rates are completed.

GOAL: Annually

2. Budget plan for existing and planned census in State Home domiciliary, nursing home and hospital levels of care are developed following submissions by the VA facility of jurisdiction.

GOAL: Annually

3. Analysis of budget plan and adjustments based on actual census data is completed.

GOAL: Quarterly

4. Inspection reports indicating level of compliance with established standards of care are provided to the State Home within 15 workdays of the VA inspection by the facility having jurisdiction over the Home.

GOAL: 90% (after establishing baseline)

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PERSIAN GULF VETERANS

The mission of the Persian Gulf (PG) Veterans Program is to provide strategic direction for the clinical, research, education and outreach programs for PG veterans. This is accomplished by working in collaboration with other VA offices; Federal, state, and local government agencies; and nonprofit community and private providers. The Persian Gulf Veterans Program also serves as VHA's liaison to the Persian Gulf Veterans Interagency Coordinating Board.

Population Measures

1. Waiting time for appointment for Registry examination and referral center admission.
GOAL: ≤ 30 days in 95% of VAMCs
2. Education
 - a. Provide opportunities for continuing medical education of Persian Gulf War (PGW) health issues.
GOAL: National Training Program
 - (1) Onsite conference (8/27-8)
 - (2) Teleconferences (satellite video broadcasts) Two in 1996
 - b. Provide current information on PGW programs, legislation, reports and publications.
GOAL: Quarterly mailouts and newsletter, periodic Environmental Agents Service (EAS) conference calls
3. Future - PGW veteran satisfaction with VA healthcare.
GOAL: Satisfaction $\geq$ other veteran groups

Program Measures

1. Waiting times for appointments for consultations, e.g., neurology, rheumatology, gastroenterology, psychiatry, psychology, etc.
GOAL: ≤ 45 days
2. Persian Gulf Registry: Phase I and Phase II code sheet rejection rates.
GOAL: rate $\leq 5\%$
3. Time to correct rejected code sheets.
GOAL: ≤ 30 days
4. Compliance threshold on the annual Quality Management monitor for Persian Gulf Registry Examinations as measured against selected clinical indicators.
GOAL: 90%

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5. Participation rates of Persian Gulf Coordinators and Registry Physicians in information and educational activities, i.e., quarterly Environmental Agents Service conference calls, satellite video-television broadcasts, and continuing medical education conference.

GOAL: 75%

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POST TRAUMATIC STRESS DISORDER (PTSD)

The mission of the Post Traumatic Stress Disorder Program is to provide treatment for veterans suffering from PTSD and to prevent relapse. This is accomplished by providing supportive mental health services and coordinating PTSD research and education.

Population Measures

1. Percentage of veterans scoring equal or better in PTSD symptoms on the short form of the Mississippi Scale 4 months after discharge.
 GOAL: 85%
2. Percentage of veterans scoring equal or better in substance abuse symptoms as measured by the Alcohol and Drug Subscales of the Addiction Severity Index (ASI) 4 months after discharge.
 GOAL: 69%
3. Percentage of veterans equal or improved in occupational functioning as measured by the number of days employed during the past 30 days at 4 months after program discharge.
 GOAL: 86%
4. Proportion of veterans in need of PTSD care treated for PTSD in VA outpatient mental health clinics in each year.
 GOAL: 55%
5. Proportion of veterans who receive a psychiatric outpatient visit within 30 days of discharge from an inpatient program (from HEDIS 2.5).
 GOAL: >51%

Program Measures

1. Proportion of veterans successfully contacted for outcome assessment after discharge from an inpatient PTSD program.
 GOAL: 50%
2. Number of patients seen per FTEE allocated to the outpatient PTSD program (including facility contributed FTEE).
 GOAL: 75 Patients/FTEE
3. Number of hospital days for patients in the 6 months after discharge from an inpatient PTSD program.
 GOAL: <13.5 days

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PRESERVATION-AMPUTATION CARE AND TREATMENT (PACT) PROGRAM

The mission of the Preservation Amputation Care and Treatment Program is to reduce the incidence of amputations and other complications due to diabetic foot ulcers and peripheral vascular disease. This is accomplished by an interdisciplinary program of care and treatment and by tracking of patients with amputations and those persons identified as "at risk" for limb loss.

Population Measures

1. The incidence of lower extremity amputations among veterans with diabetes.
GOAL: Reduce by 5% from prior year
2. Percentage of diabetics with chart documented annual lower extremity ulcer risk examination.
GOAL: Increase by 5% from prior year
3. Percentage of new lower extremity amputees who achieve functional status adequate to return to pre-hospital living setting.
GOAL: 85%
4. Percentage of new lower extremity amputees who are ambulatory six months after provision of artificial limb.
GOAL: Increase by 3% from prior year

Program Measures

1. Percentage of new amputees, i.e., toe, transmetatarsal, below knee, above knee, and hip disarticulation referred by the PACT Coordinator for evaluation.
GOAL: 100%
2. Percentage increase in the number of new outpatients identified as being at-risk of limb loss who are referred to the PACT Program.
GOAL: >Prior Year

VHA DIRECTIVE 96-051**August 14, 1996****PROSTHETIC AND SENSORY AIDS SERVICE**

The mission of the Prosthetic and Sensory Aids Service is to serve as case manager for the physically disabled veteran and to provide quality prosthetic and sensory aid services to these patients. This is accomplished by furnishing properly prescribed prosthetic equipment, sensory aids and assistive devices.

Population Measures

1. Percentage of veterans fitted for a limb within 30 days of amputation.
GOAL: Establish baseline
2. Percentage of prosthetic patients who respond favorably on the Prosthetic Patient Satisfaction survey.
GOAL: >97%
3. Percentage of prosthetic patients with improved functional status 6 months post fitting.
GOAL: Establish baseline

Program Measures

1. Average VA waiting time for an appointment for examination and prescription of a prosthetic appliance will be equal to or less than local community standards, e.g., Optometry, Audiology, Orthopedics, Spinal Cord Injury, Physical Medicine and Rehabilitation, etc.
GOAL: Establish baseline
2. Number of delays in prosthetic orders, per month per total number of orders, i.e., orders not placed within 5 days.
GOAL: <2% of workload
3. Number of Type I recommendations from JCAHO/CARF surveys concerning the management of Durable Medical Equipment and the Home Oxygen Program in accordance with JCAHO Home Care standards.
GOAL: 0
4. Quarterly Prosthetic Needs/Excess Reports will accurately report on PSAS cost accounts. Funding will be based upon a strong correlation between obligations and workload.

(Centralized Prosthetic Fund Annual Facility Budget)

\$5 million and up	(+/-) <2%
\$4 million to <\$5 million	(+/-) 2%
\$3 million to <\$4 million	(+/-) 3%
\$2 million to <\$3 million	(+/-) 4%
\$1 million to <\$2 million	(+/-) 5%
\$500,000 to <\$1 million	(+/-) 6%
\$500,000	(+/-) 10%

5. Number of PSAS Headquarters-initiated program site visits to ensure compliance with national fiscal policy (continuation of PIMP objective).
GOAL: 24/FY

A-14

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READJUSTMENT COUNSELING SERVICE VETERAN CENTERS

The mission of the Readjustment Counseling Service is to restore normal emotional functioning to persons psychologically injured during military service. This is accomplished by providing outreach, crisis intervention, and "holistic" counseling services to eligible veterans and their families. These services are provided through a network of readjustment counseling centers commonly known as "vet centers."

Population Measures

1. The rate of special population veterans at risk for PTSD and other readjustment problems accessing RCS care. Special populations include veterans with high combat exposure, sexual trauma, physical disability, or ethnic diversity.
GOAL: Contact with the percentage of veterans predicted to be at risk in the Vet Center's catchment area
2. Percent of clients satisfied with services.
GOAL: Obtain baseline information
3. Post-treatment problem severity.
GOAL: Improvement in problem severity ratings post-treatment

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SERIOUSLY MENTALLY ILL VETERANS

The mission of the Seriously Mentally Ill Veterans Program is to optimize the functioning of seriously mentally ill veterans. This is accomplished by providing state-of-the-art treatment across a continuum of inpatient and outpatient settings.

Population Measures

1. Percentage of SC veterans with a diagnosis of psychosis who use VISN mental health services.

GOAL: $\geq 39\%$

Note: Adjusted for sociodemographic factors and availability of non-VA services. From Table 2-4, National Mental Health Program Performance Monitoring System (NMHPPMS), June 14, 1996, Northeast Program Evaluation Center (NEPEC)(182), VA Medical Center, 950 Campbell Ave., West Haven, CN 06516, (203) 937-3850; FTS (700) 428-3717.

2. 30 day psychiatric re-admission rates (excluding substance abuse), within the VISN.

GOAL: $\leq 15\%$ *Note: See table 3-1, (NMHPPMS)*

3. Functional performance 6 months and 1 year after initiating treatment in Intensive Psychiatric Community Care (IPCC) as measured by a standard Instrumental Activities of Daily Living (IADL) instrument.

GOAL: 20% improvement over previous year

4. Overall score on the outpatient domain of the mental health performance index which includes measures of access, utilization of services, and continuity of care.

GOAL: 20% improvement over previous year

5. Percentage of veterans who receive an outpatient appointment within 30 days of discharge from an inpatient program.

GOAL: $\geq 45\%$ *Note: See table 4-1, (NMHPPMS)*

Program Measures

1. Average VISN general psychiatric bed days of care during the 6 months after discharge.

GOAL: ≤ 14 days *Note: See table 3-1, (NMHPPMS)*

2. The number of 2 month periods (by VAMC) in which general psychiatric outpatients have two or more VA outpatient mental health visits (continuity of care) within the first 6 months following discharge.

GOAL: ≥ 1.13

Note: See table 4-7, (NMHPPMS, adjusted for patient characteristics, resident distance from VA, etc.)

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3. The percentage decrease in the number of SMI veterans per VISN with a diagnosis of psychosis with lengths of stay of 100 days or longer.
 GOAL: >=10%
4. The percentage decrease in average length of stay of psychiatric inpatients within 28 VAMCs identified as significant outliers.
 GOAL: >=10%

VHA DIRECTIVE 96-051**August 14, 1996****SPINAL CORD INJURY/DYSFUNCTION**

The mission of Spinal Cord Injury/Dysfunction Program (SCI/D) is to assist veterans with SCI/D to develop the capacities needed to attain personal independence and lifelong health and well being. This is accomplished by providing initial functional rehabilitation, preventive care, sustaining care, and long-term care across a continuum of inpatient and outpatient settings.

Population Measures

1. Percentage of SCI/D patients responding favorably on satisfaction surveys concerning communication, courtesy, quality of care, timeliness, and clinical environment.
GOAL: 90%
2. Overall score on the SCI/D evaluation index (characteristics include measures of effectiveness - outcomes achieved by persons served; efficiency; and other elements to be defined). A baseline report is expected in January.
GOAL: Improvement
3. Percentage of eligible SCI/D veterans receiving annual evaluation as required by M-2, part XXIV.
GOAL: >80%

Program Measures

1. Percent of SCI/D patients who are assigned to a primary care provider.
GOAL: 90%
2. Established use of an appropriate functional outcome measure (such as FTM) for SCI/D patients.
GOAL: 100%
3. Percentage of eligible veterans with a diagnosis of SCI/D who used a VISN SCI support clinic or center in 1996.
GOAL: Exceed FY 95 Baseline
4. Percentage of SCI/D patients with semi-emergent conditions admitted to an SCI Center within 2 weeks of acceptance. Semi-emergent conditions and triage criteria will be defined.
GOAL: >95%

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SUBSTANCE ABUSE SERVICES

The mission of the Substance Abuse Services Program is to provide programs that identify, manage and treat substance use disorders. This is accomplished by providing early intervention, stabilization (including detoxification) and rehabilitation services, continuing care and monitoring services, staff education, and research.

Population Measures

1. The percentage of patients with active substance abuse who enter substance abuse treatment within 3 days of discharge from a hospitalization (including detoxification).
GOAL: 70%
2. The total number of patients in specialized acute, residential, domiciliary or ambulatory substance abuse care as a percentage of the total number of patients in care at the medical center.
GOAL: No decrease from prior fiscal year
3. The percentage of patients with a positive alcohol abuse screen in primary care settings who are abstinent at 6-month follow-up.
GOAL: 60%

Program Measures

1. For patients discharged from specialized acute care, residential and domiciliary substance abuse bed sections (whose entire index episode of inpatient care is in a substance abuse bed section):
 - a. percentage of patients who obtain two or more substance abuse or mental health outpatient visits in the 30 days after discharge.
GOAL: 70%
 - b. Number of days between discharge from inpatient care and the first visit.
GOAL: 7 days or less
2. Percentage of patients admitted directly to specialized substance abuse outpatient care who have two or more additional specialized outpatient substance abuse clinic contacts in the subsequent 30 days.
GOAL: 70%
3. The number of patients in specialized outpatient substance abuse as a percentage of the number of outpatients.
GOAL: No decrease in % from previous fiscal year.
4. The number of specialized outpatient substance abuse visits as a percentage of total outpatient visits.
GOAL: No decrease in % from previous fiscal year.

local agencies, as well as community non profit organizations and private entities.

Population Measures

1. Percentage of veterans who acquired secure living arrangements at discharge from a domiciliary or a residential treatment program.
GOAL: 40%
2. Percentage of veterans who obtained employment at discharge from a domiciliary or residential treatment facility.
GOAL: 18%
3. Percentage of veterans who acquired secure living arrangements at 6 months and 1 year after entry into the VA Supported Housing (VASH) Program.
GOAL: 80%
4. Percentage of veterans identified on the annual homeless census who receive a psychiatric outpatient visit within 30 days of discharge from an inpatient setting (from Health Plan Employer Data and Information Set (HEDIS) 2.5).
GOAL: >45%

Program Measures for Domiciliary Care for Homeless Veterans Program (DCHV)

1. Annual Turnover Rate of homeless veterans per DCHV bed per year which is defined as the number of discharges (determined by the number of monitoring forms received at NEPEC for which the discharge data falls within a given fiscal year) divided by the number of operational beds (as determined by an annual survey conducted on September 1st of each year).
GOAL: >1.4
2. Percentage of homeless veterans successfully completing DCHV treatment.
GOAL: >38%
3. Improvement in alcohol problems of veterans from the time they entered DCHV treatment to the time of discharge.
GOAL: >57%
4. Improvement in drug problems of veterans from the time they entered treatment to the time of discharge.
GOAL: >55%

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Program Measures for Health Care for Homeless Veterans (HCHV)

1. Number of literally homeless veterans receiving intake assessments per clinical FTEE.
GOAL: >52 per year
2. Number of unique homeless veterans treated in an HCHV Program per clinical FTEE per year.
GOAL: >100
3. Percentage of homeless veterans successfully completing residential treatment programs.
GOAL: >30.4%
4. Percentage of veterans referred for follow-up treatment at the time of discharge from residential treatment.
GOAL: >60.8%
5. Improvement in alcohol problems of veterans treated from the time they entered residential treatment to the time of discharge.
GOAL: >52.5%
6. Percentage of veterans scoring equal or better in substance abuse symptoms as measured by the Alcohol and Drug Subscales of the Addiction Severity Index (ASI) 6 months and 1 year after entering the VASH program.
GOAL: 69%
7. Number of days hospitalized in the 6 months after discharge of veterans identified on the annual homeless census.
GOAL: <14 days

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WOMEN VETERANS HEALTH PROGRAM

The mission of the Women's Veterans Health Program is to ensure equity of access to VA services and care for women veterans. This is accomplished through integration of clinical care, education, and research on women veterans-related issues.

Population Measures

1. Satisfaction with VA services.
GOAL: Ratings comparable to men
2. Percentage of appropriate women 50-69 years of age receiving mammography within the last 2 years.
GOAL: 100%
3. Percentage of appropriate women <65 years of age receiving cervical cancer screening within the last 36 months.
GOAL: 100%

Program Measures

1. Number of focus groups conducted in each VISN to explore any gender specific differences in customer satisfaction measures.
GOAL: =>1/year
2. Percentage of contracting pathology laboratories reviewing Pap smears that are accredited by CAP and hold a CLIA certificate.
GOAL: 100%
3. Percentage of on-site pathology laboratories reviewing Pap smears that are accredited by CAP and percent of pathologists enrolled in the National Cytopathology Proficiency Program.
GOAL: 100%
4. Percentage of women veterans receiving notification of Pap smear findings within one month of performance of the test.
GOAL: 100%
5. Percentage of on-site mammography units accredited.
GOAL: 100%
6. Percentage of women receiving mammograms notified of results within 1 month.
GOAL: 100%

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 97-008

February 19, 1997

VHA'S SERVICE EVALUATION AND ACTION TEAM

1. PURPOSE: The purpose of this Veterans Health Administration (VHA) Directive is to establish a Service Evaluation and Action Team (SEAT) within each Veterans Integrated Service Network (VISN) office to enhance VHA's responsiveness to patient needs and service satisfaction. The SEAT will provide a mechanism for each VISN office to continually assess opportunities to enhance the effectiveness of Department of Veterans Affairs (VA) clinical programs and to respond to veterans' concerns. The SEAT enables all medical center Directors, VISN Directors, and VHA Headquarters' program staff to track trends in customer concerns and complaints and to conduct a self-assessment on a periodic basis. The initial SEATs will be piloted with Persian Gulf Veterans Programs and, if successful, expanded to other program areas in the future.

2. POLICY: All VISN Offices will implement a SEAT not later than March 1, 1997.

3. ACTION

a. Each VISN director will appoint the members of the Network SEAT. Membership shall include, but is not necessarily limited to, the following:

- (1) The VISN Clinical manager, who will serve as Chairperson of the SEAT;
- (2) A veterans service organization representative;
- (3) A VA medical center Chief of Staff;
- (4) A VA medical center patient representative and/or advocate;
- (5) A Persian Gulf Registry physician;
- (6) A Vet Center representative;
- (7) A quality improvement manager; and
- (8) A regional veterans benefits counselor.

b. The SEATs will listen to and monitor trends in veterans' (individual or group) concerns about health care access, appropriateness, quality and fulfillment of VA program mandates within the VISN or at its medical facilities. The information gathered on reported concerns and recommendations for favorable resolution will be referred to local medical facility staff for action. The SEAT will monitor such action and results. The goal of each SEAT referral is to improve communication with veterans, their families, and other stakeholders, where possible, to improve the responsiveness of VA health care delivery.

THIS VHA DIRECTIVE EXPIRES JANUARY 30, 1998

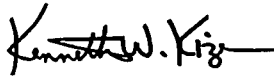
VHA DIRECTIVE 97-008
February 19, 1997

c. Requests and referrals to the SEAT for action can be made by veterans, veterans service organizations, VA hotline staff, veterans benefits counselors, VA regional offices and others. The SEAT will also receive input from national and local customer satisfaction and quality improvement programs.

d. SEAT referrals and resulting actions will be tracked and reported on a quarterly basis to the VISN Director.

4. FOLLOW-UP RESPONSIBILITY: The Chief Network Officer (10N) is responsible for the contents of this directive. Questions on Persian Gulf War Veterans Programs can be directed to the Office of Public Health and Environmental Hazards (13), VA Central Office, 810 Vermont Avenue, NW, Washington, DC, 20420.

5. RESCISSION: This VHA Directive will expire January 30, 1998.



Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 2/19/97
FLD: VISN, MA, DO, OC, OCRO and 200-FAX 2/19/97
EX: Boxes 104, 88, 63, 60, 54, 52, 47 and 44 - FAX 2/19/97



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

IL 10-97-014

In Reply Refer To: 131

March 18, 1997

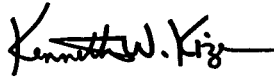
UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER

VHA's SERVICE EVALUATION AND ACTION TEAM (SEAT)

1. The Service Evaluation and Action Team (SEAT) Program was developed and approved on January 6, 1997. The final program plan including the purpose, policy, and required actions and responsibilities was presented by the Under Secretary for Health to the Directors of the 22 Veterans Integrated Service Networks (VISNs) on January 22, 1997.
2. Veterans Health Administration (VHA) Directive No. 97-008, February 19, 1997, establishes a SEAT within each VISN office to enhance VHA's responsiveness to patient needs and service satisfaction. The SEAT enables all medical center Directors, VISN Directors, and program staff at VHA Headquarters to track trends in customer concerns and complaints and to conduct an evaluation on a periodic basis. The SEAT provides a mechanism for each VISN office to continually assess opportunities to enhance the effectiveness of Department of Veterans Affairs (VA) clinical programs and to respond to veterans' concerns. The initial SEATs will be piloted with Persian Gulf Veterans Programs and, if successful, expanded to other program areas in the future.
3. The SEAT will receive input from national and local customer satisfaction surveys, the patient representative tracking program, veterans, veterans service organizations, helpline inquiries, and quality improvement programs. The Chairperson of the Network SEAT is responsible for collecting data obtained from these sources and maintaining this information at the VISN office. Each Network SEAT Chairperson is encouraged to process this aggregate information (by issue, by service, or by gender), and submit a consolidated quarterly report to their respective Network Director. A copy of this quarterly report needs to be submitted through the Chief Network Office (10NC), to Environmental Agents Service (131), VHA Headquarters, 810 Vermont Avenue N.W., Washington, DC 20420.
4. SEATs are being formed to:
 - a. Improve the responsiveness of VA health care delivery;
 - b. Improve communication with veterans, their families, and other stakeholders, where possible; and
 - c. Listen to and monitor trends in veterans' (individual or group) concerns about health care access, appropriateness, quality and fulfillment of VA program mandates within the VISN or at its medical facilities.

IL 10-97-014
March 18, 1997

5. The teams, are comprised of at least eight members, representing a variety of disciplines and interests, including veterans, quality improvement specialists, patient representatives and clinicians.
6. The information gathered on reported concerns, and recommendations for favorable resolution, will be referred to local medical facility staff for action. The SEAT monitoring of such action and results will allow VAH to continuously improve and enhance Persian Gulf Programs in the future.



Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 3/19/97
FLD: VISN, MA, DO, OC, OCRO and 200-FAX 3/19/97
EX: Boxes 104, 88, 63, 60, 54, 52, 47 and 44 - FAX 3/19/97

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

M-10, Part III
Change 2

March 21, 1996

1. Transmitted is a change to the Department of Veterans Affairs (VA), Veterans Health Administration manual M-10, "Environmental Agents Service," Part III, "Persian Gulf Program."
2. Principal change is the addition of the new Chapter 5, "Persian Gulf Registry III Specifically for Spouses and Children of Persian Gulf War Veterans."

3. Filing Instructions

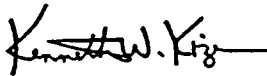
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2C-7 through 2C-19
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3B-1 through 3B-4

Insert pages

iii through iv
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5C-1 through 5C-5
5D-1 through 5D-10
5E-1

4. RESCISSIONS: None.



Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

Distribution: RPC: 1323
FD

Printing Date: 3/96

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

M-10, Part III
Change 1

September 14, 1995

1. Transmitted is a change to the Department of Veterans Affairs (VA), Veterans Health Administration M-10, "Environmental Agents Service," Part III, "Persian Gulf Program."

2. Principal changes are:

a. **Appendix 2A:** This change adds to "Definitions and Acronyms", "RHP, Reproductive Health Problems."

b. **Appendix 2C:** Changes the VHA manual references for pseudo Social Security Numbers, Facility, County and State Codes.

c. **Appendix 2D:** Changes to the "Reporting Requirements," specifies date of the discontinuation of VA Form 10-9009A, Persian Gulf Code Sheet, dated December 1991, and the date of implementation of VA Form 10-9009A, Persian Gulf Code Sheet, dated July 1995.

d. **Appendix 3A:** Changes the "Uniform Case Assessment Protocol (UCAP)" which provides additional elements for the evaluation of Persian Gulf veterans with complaints of Reproductive Health Problems (RHP).

3. Filing Instructions

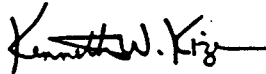
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2D-1 through 2D-4
3A-3 through 3A-5

4. **RESCISSIONS:** None.



Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

Distribution: RPC: 1323
FD

Printing Date: 9/95

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

M-10, Part III
August 8, 1995

1. Transmitted is a revision to the Department of Veterans Affairs, Veterans Health Administration M-10, "Environmental Agents Service," Part III, "Persian Gulf Program."

2. This revision provides the following:

- a. Chapter 1: States the authority for providing health care and describes the services authorized.
- b. Chapter 2: Defines the Persian Gulf Registry (PGR) and describes eligibility criteria and program management.
- c. Chapter 3: Provides an uniform case assessment protocol for veterans that have unexplained illnesses after their Persian Gulf Service.
- d. Chapter 4: Defines the clinical and administrative policies concerned with the program management of Persian Gulf Referral Centers (PGRC) and PGRC reporting requirements.

3. Filing Instructions

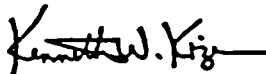
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2B-1 through 2B-4
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2E-1 through 2E-2
2F-1 through 2F-4
2G-1 through 2G-2
3-I
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3B-1 through 3B-8
3C-1 through 3C-2
4-I
4-1 through 4-5
4A-1 through 4A-2

4. **RESCISSIONS:** M-10, Part III, Chapters 1 and 2, dated December 7, 1992, and VHA Directive 10-95-053.



Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

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FD

Printing Date: 8/95



Environmental Agents Service

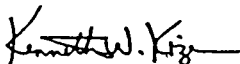
Persian Gulf Program

August 8, 1995

M-10, Part III

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

The Department of Veterans Affairs, Veterans Health Administration Manual M-10, "Environmental Agents Service," Part III, "Persian Gulf Program," is published for the compliance of all concerned.



Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

Distribution: RPC: 1323
FD

Printing Date: 8/95

March 21, 1996

M-10, Part III
Change 2

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2. PHASE I, PERSIAN GULF REGISTRY EXAMINATION
3. PHASE II, PERSIAN GULF UNIFORM CASE ASSESSMENT PROTOCOL
4. PERSIAN GULF REFERRAL CENTERS
5. PERSIAN GULF REGISTRY SPECIFICALLY FOR SPOUSES AND CHILDREN OF
PERSIAN GULF WAR VETERANS

**M-10, Part III
Change 2**

March 21, 1996

RESCISSIONS

The following material is rescinded:

1. Manuals

M-10, Part III, Chapter 1 and 2, dated December 7, 1992.

2. Directives

10-95-053

August 8, 1995

M-10, Part III
Chapter 1

CHAPTER 1. PERSIAN GULF REGISTRY (PGR) PROGRAM

1.01 PURPOSE

a. This chapter provides procedures to establish a Persian Gulf Registry (PGR) Program at all Department of Veterans Affairs (VA) health care facilities for concerned participants of "Operation Desert Shield /Storm."

1.02 BACKGROUND

a. According to the Department of Defense (DOD) approximately 690,000 American servicemen and women were involved in the Persian Gulf War. There may be a substantial number of troops actually exposed to unignited petroleum and/or smoke from the sabotage of Kuwaiti oil wells by retreating Iraqi forces as well as other industrial and environmental hazards.

b. Establishment of a PGR will assist VA in initiating a program to identify possible diseases which may result from service of United States (U.S.) military personnel in certain areas of Southwest Asia (see par. 2.02). These diseases may be endemic to the area or due to hazardous exposures, including heavy metals. Furthermore, air pollutants, i.e., carbon monoxide sulfur oxides, hydrocarbons, particulate matter, and nitrogen oxides, singly or in combination, can cause chronic as well as acute health problems.

(1) These health problems may include:

- (a) Chronic bronchitis,
- (b) Chronic obstructive pulmonary disease,
- (c) Pulmonary emphysema,
- (d) Bronchial asthma, and
- (e) Lung cancer.

NOTE: U.S. veterans who served in the Persian Gulf theatre of war are henceforth in M-10, Part III, referred to as Persian Gulf veterans.

(2) Persian Gulf veterans have reported a wide variety of symptoms and exposures as a consequence of Persian Gulf service. These include, but are not limited to exposure to:

- (a) Oil, smoke and other petrochemical agents;
- (b) Leishmaniasis (Sand flies);
- (c) Pyridostigmine bromide, malaria prophylaxis and other prophylactic drug treatments;
- (d) Depleted Uranium (DU);
- (e) Inoculations (Anthrax, botulism, etc.);
- (f) Pesticides;
- (g) Diesel and jet fuels and other petrochemicals and solvents;
- (h) Chemical Agent Resistant Compound (CARC) paint;
- (i) Chemical and/or biological warfare agents; and

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- (j) Contaminated food and water obtained in the Persian Gulf.
- (3) The following symptoms have been reported by a number of Persian Gulf veterans:
 - (a) Gastrointestinal problems;
 - (b) Flu-like conditions;
 - (c) Skin rashes;
 - (d) Sinus congestion, post nasal drip;
 - (e) Joint pains and/or muscle soreness;
 - (f) Hair loss;
 - (g) Headaches;
 - (h) Memory loss;
 - (i) Chronic fatigue;
 - (j) Thickened saliva;
 - (k) Loose teeth, sore and/or bleeding gums;
 - (l) Dizziness, vertigo;
 - (m) Sleep disturbance; and
 - (n) Other symptoms and/or exposures.

(4) During the examination process, these exposures and health conditions will be identified and documented in the Consolidated Health Record (CHR) and VA Form 10-9009A (July 1995), Persian Gulf Registry Code Sheet.

c. The creation of a registry containing medical and other data on exposed veterans will signal VA's commitment to address questions concerning possible future effects of air pollutant exposure, other environmental agents, and serve as the basis for future medical surveillance. **NOTE:** *VA is in the process of requesting support for future computerization of this registry.*

1.03 AUTHORITY AND HEALTH CARE SERVICES PROVIDED

Title 38, United States Code (U.S.C.) Chapter 17, Section 1710, provides for health care only, and a determination that the veteran is eligible for such care does not constitute a basis for service-connection or in any way affect determinations regarding service-connection.

a. Health care services will be provided to veterans who while serving on active duty in the Southwest Asia theater of operations during the Persian Gulf War may have been or were exposed to a toxic substance or environmental hazard. Verification of service in the Persian Gulf during the Persian Gulf era (August 2, 1990 - no ending date established by law) will be required. Inasmuch as VA presumes that a veteran was exposed to a toxic substance or environmental hazard during any service in the Persian Gulf, a verified claim of such in-country service constitutes the required contention of exposure and establishes eligibility for medical care within these provisions.

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Chapter 1

b. Authorized health care services are limited to:

(1) Hospital, nursing home care and outpatient care in VA facilities on a pre- or post-hospitalization basis or to obviate a need for hospitalization.

(2) Such health care services will be provided without regard to the veteran's age, service-connected status or ability of the veteran to defray the expenses of such care.

(3) Veterans furnished outpatient care under this authority will be accorded priority ahead of most other non service-connected veterans and equal to former Prisoners of War who are receiving care for non service-connected conditions.

(4) Congress made it clear that this authority provides for health care only, and that a determination that the veteran is eligible for such care does not constitute a basis for service-connection or in any way affect determinations regarding service-connection.

NOTE: *Health care services may not be provided under this authority for the care of conditions which are found to have resulted from a cause other than the specified exposures.*

1.04 HEALTH EVALUATION

a. Veterans claiming health conditions related to exposure to toxic substance or environmental hazard will be evaluated clinically by means of a physical examination and appropriate diagnostic studies (see Ch. 2, App. 2B). Where findings reveal a condition requiring treatment, the responsible staff physician shall make a determination as to whether the conditions resulted from a cause not related to Persian Gulf Service.

b. In making this determination, the physician will consider the following types of conditions which are not ordinarily considered to be due to toxic substances or environmental hazards:

- (1) Congenital or developmental conditions, e.g., spina bifida, scoliosis.
- (2) Conditions which are known to have existed before the Persian Gulf.
- (3) Conditions resulting from trauma, e.g., deformity or limitation of motion of an extremity.
- (4) Conditions having a specific and well-established etiology; e.g., tuberculosis or gout.
- (5) Common conditions having a well-recognized clinical course, e.g., inguinal hernia or acute appendicitis.

1.05 EXCEPTIONS TO SERVICES

a. Although the types of conditions listed in paragraph 1.04 are not ordinarily considered to be due to a toxic substance or environmental hazard, if the staff physician finds that a veteran requires care under this provision for one or more of those conditions, the physician should seek guidance from the Chief of Staff (COS) and the Veterans' Registry Physician (VRP) regarding the authorization for treatment.

b. The decision and its basis will be clearly documented in the medical record or chart by the VRP.

c. Veterans who are not provided needed medical care under these provisions may be furnished care if they are eligible under other statutory authority.

d. All non service-connected Persian Gulf veterans who respond affirmatively to the exposure question are means tested before being seen by a physician.

1.06 RESPONSIBILITIES

a. A PGR will be established modeled after the Agent Orange and Ionizing Radiation Registries. All VA facility staff are to be alerted of the PGR through appropriate internal communications, e.g., medical center memoranda providing names, locations, and office telephone numbers of the Veterans' Registry Physician (VRP) and the Veterans' Registry Coordinator (VRC).

(1) The PGR is the responsibility of VA Central Office Environmental Agents Service (EAS), in coordination with:

- (a) VRPs;
- (b) VRCs; and
- (c) The VA Austin Automation Center (AAC), Austin, TX.

(2) It will consist of medical examinations and other data of concerned Persian Gulf War participants. The PGR will be the most effective means of identifying such concerned veterans.

b. The EAS has the responsibility to develop, coordinate, and monitor Veterans Health Administration (VHA) activities relating to the Persian Gulf issue. All policy and clinical questions relating to the identity of possible diseases which may result from service of U.S. (United States) military personnel in certain areas of Southwest Asia should be referred to EAS.

c. The VRP and VRC at each VA facility will assume respective responsibility for coordinating the medical and administrative aspects of the registry. The VRP, VRC, and other medical center staff, will play a key role, beginning with the initial contact in:

(1) Providing registry participants with medical examinations and necessary treatment where medically indicated for eligible veterans;

(2) Advising veterans of examination results; and

(3) Submitting properly completed code sheets to the AAC.

d. There will be a time lapse between the date of examination and the processing of examination results. Accordingly, analyses used in speeches or presentations should be qualified to avoid misleading or misinforming the audience.

1.07 MEDIA AND OTHER EXTERNAL CONTACTS

a. **Media Contacts.** Reports of Contact from various media sources (e.g., radio, television, newspapers, etc.) concerning PGR Program activities will be referred by phone to the facility Public Affairs Officer. Interviews should not be given unless approved by the medical center Public Affairs Officer who may appropriately coordinate response with the regional VA public affairs representative.

b. **Contacts to Advise Centers of "Special Cures" for Persian Gulf-Related Illnesses.** Medical centers can expect, on occasion, to be contacted by private sector physicians, researchers, and the general public with information regarding "quick cures" for Persian Gulf-related illnesses. Such individuals should be advised that:

(1) There are medically accepted mechanisms to introduce new clinical treatments;

(2) All new treatments suggested must be reviewed by a formally designated and staff Human Subjects Review Committee;

(3) It is important to have independent confirmation of treatment efficacy;

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Chapter 1

(4) Provisions exist to permit the originator of new therapies to retain professional credit and be appropriately compensated; and/or

(5) The individual might want to consider presenting the "new approach" at a VA or medical school Grand Rounds or Staff Review Committee meeting.

1.08 SPECIAL HEALTH NEEDS OF PERSIAN GULF FEMALE VETERANS

VHA is committed to providing for the physical and psychological treatment needs of women veterans who have been sexually or physically abused, or engaged in combat.

a. The VRP should be aware of and sensitive to the needs of Persian Gulf women veterans who were:

- (1) Raped;
- (2) Otherwise sexually assaulted;
- (3) Sexually harassed;
- (4) Combatants during military service, or
- (5) Prisoners of War.

b. This can lead to long-term psychiatric and psychosomatic sequelae. When a problem is detected, appropriate counseling and psychotherapy must be provided.

NOTE: *Since this is a highly specialized area, it may be necessary to make appropriate referral to other VA or private sector providers. This should be reported on the CHR as well as under Item 32, Part II of VA Form 10-9009A (July 1995), Persian Gulf Registry Code Sheet, Phase I.*

August 8, 1995

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Chapter 2

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2G Examples of Persian Gulf Registry Follow-up Letters	2G-1

**M-10, Part III
Chapter 2**

August 8, 1995

RESCISSIONS

The following material is rescinded:

1. Manuals

M-10, Part III, Chapter 2, dated December 7, 1992.

August 8, 1995

M-10, Part III
Chapter 2**CHAPTER 2. PHASE I, PERSIAN GULF REGISTRY (PGR) EXAMINATION****2.01 PURPOSE**

This chapter sets forth clinical and administrative policies related to the maintenance of Veterans Health Administration's (VHAs) Persian Gulf Registry (PGR) Program for physical examinations of concerned veterans.

2.02 ELIGIBILITY CRITERIA

The Department of Veterans Affairs (VA) will provide a PGR examination to veterans who served on active military duty in Southwest Asia during the Persian Gulf War between August 2, 1990, and the official termination date (to be established). Active duty military personnel who served in Southwest Asia are encouraged to participate in the PGR program, (see par. 2.07).

a. This would include service in one or more of the following areas:

- (1) Iraq;
- (2) Kuwait;
- (3) Saudi Arabia;
- (4) The neutral zone (between Iraq and Saudi Arabia);
- (5) Bahrain;
- (6) Qatar;
- (7) The United Arab Emirates;
- (8) Oman;
- (9) Gulf of Aden,
- (10) Gulf of Oman; and
- (11) Waters of the:
 - (a) Persian Gulf,
 - (b) Arabian Sea; and
 - (c) Red Sea.

NOTE: *Medical Administration Service (MAS) should be consulted to determine whether each veteran applying for this examination meets pertinent eligibility requirements.*

b. Eligible Persian Gulf veterans applying for treatment in a VA medical center and/or outpatient clinic should be encouraged to undergo an initial (i.e., "first-time") PGR examination. The protocol for conducting the physical examination and ordering diagnostic studies is contained in Appendix 2B.

c. Veterans should be advised that examination or treatment does not constitute a formal claim for compensation.

(1) Although the results of a PGR examination may be used to support a compensation claim, the examination will not in and of itself be considered such a claim.

NOTE: *If a compensation examination is performed for a Persian Gulf War veteran and the veteran requests inclusion in the PGR, it is not necessary to schedule an additional registry examination as long as the information is sufficient to adequately complete the PGR code sheet for submission to the Austin Automation Center (AAC).*

(2) Veterans who wish to submit a claim for conditions possibly related to Persian Gulf service should do so via the normal claims process through a Veterans Benefits Counselor (VBC) at the nearest VA medical center or regional office.

2.03 PROGRAM MANAGEMENT

For current information and program activities, Veterans' Registry Physicians (VRPs), Veterans' Registry Coordinators (VRCs) and MAS employees should receive and familiarize themselves with quarterly mailouts and various materials distributed by VA Central Office. In addition, all program officials should attend the periodic Environmental Agents Service (EAS) conference calls from VA Central Office.

2.04 RESPONSIBILITIES

The VRP, or designee, VRC and MAS staff play a significant role in determining the perceptions veterans have concerning the quality of VA health care services and of their individual treatment by VA health care providers.

a. **VRP Responsibilities.** The VRP, or designee, is responsible for clinical management of the veteran on the registry and will serve as their primary health care provider unless another has been assigned. The VRP serves in an advisory capacity for the administrative management of the program. The VRP should be the person to discuss with the patient the results of the examination(s) as well as providing follow-up visits and/or possible referrals to other tertiary medical centers or Persian Gulf Referral Centers (PGRC). Major essential responsibilities include:

- (1) Counseling the veteran as to the purpose of the physical examination;
- (2) Providing focused initial examination and continuum of care to those symptomatic veterans experiencing multiple symptoms after their Persian Gulf experience;
- (3) Conducting and documenting the physical examination in the medical record or Consolidated Health Record (CHR) at the time of the visit;
- (4) Providing a complete medical history including:
 - (a) Family;
 - (b) Occupation;
 - (c) Social, including tobacco, alcohol, and drug use;
 - (d) Civilian exposure to possible toxic agents;
 - (e) Psychosocial condition; and
 - (f) Review of systems.
- (5) Completing Part II (Phase I) and III (Phase II) of VA Form 10-9009A (July 1995), Persian Gulf Registry Code Sheet, and reviewing Part I and completing that section, if necessary.

March 21, 1996

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Change 2
Chapter 2

(a) Reviewing the code sheet to further ensure the form's completeness, the clinical examiner will review the code sheet and, if necessary, obtain and record any missing information from the veteran.
NOTE: Code sheets should be transmitted to AAC no later than 25 working days after initial examination.

(b) Inquiring whether any of the veteran's natural children have any birth defects and noting in Item 22 and the CHR.

(6) Reviewing records of every Persian Gulf veteran examined to ensure that a complete physical examination was performed and documented;

(7) Personally discussing with each veteran the findings of the physical examination and completed diagnostic studies. The interview will be conducted in such a way as to encourage the veteran to discuss any health concerns, as well as concerns expressed by family members;

(8) Personally discussing each veteran's need for a follow-up examination either recommended by VRP or requested by the veteran;

(9) Documenting these discussions and/or findings in each veteran's CHR.

(10) Encouraging the veteran to contact VA medical center to include additional diagnoses in CHR and PGR if the veteran is subsequently diagnosed with a significant health problem by a non-VA physician. This new diagnosis must be submitted under non-VA physician's signature and on official letterhead. A code sheet identified as, follow-up examination, Type C, will be completed with this diagnosis and subsequently forwarded to AAC for inclusion in PGR.

(11) Preparing and signing a follow-up letter to each veteran explaining the results of the examination and associated laboratory tests. *NOTE: Sample follow-up letters are provided in Appendix 2G.*

(a) These letters are to be mailed to the veteran within 2 weeks of the initial examination appointment and follow-up examination when a new diagnosis is determined. The only exception to this timeframe will be when a consultation at a specialty clinic is requested as part of the initial examination process. This exception suspends, but does not remove the requirement for the follow-up letter. The follow-up letter is to be sent no later than 2 weeks after the consultation.

(b) A copy of this dated and signed letter will be filed in the veteran's CHR.

(c) It is essential that this letter be written in language that can be easily understood by the veteran. Inappropriate wording could unduly alarm or confuse the veteran. A great deal of sensitivity and care should be exercised in the preparation of this correspondence.

(d) The letter will explain that:

1. If the veteran who was examined has no detectable medical problems, the follow-up letter should so indicate and suggest that the veteran contact the nearest VA health care facility if health problems appear later.

2. If it is determined upon examination that the veteran does have medical problems, it is not necessary to specify the problems in the letter.

3. The veteran should be advised in the letter that the recent examination indicated a health condition or problem which may require further examination and/or treatment.

4. If the veteran is eligible for VA medical treatment, the letter should so advise and recommend that the veteran seek follow-up medical care at the VA medical facility.

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5. If the veteran is not eligible for treatment, the letter should so advise and recommend that the veteran seek appropriate medical care elsewhere.

6. The examination does not automatically initiate a claim for VA benefits. For information relating to claims, refer the Persian Gulf veterans to a VBC at the nearest VA medical center or regional office.

7. The results of the examination will be maintained by VA and will be available for future use as needed; and

8. If the veteran changes place of residence, the veteran should provide the new address to the VRC to be recorded on a computerized record or card file and included on a corrected code sheet (Type "E" examination code) for submission to AAC.

b. Veterans' Registry Coordinator (VRC) Responsibilities

(1) The VRC is responsible for the administrative management of the program, including:

- (a) Scheduling of appointments;
- (b) Monitoring timeframe compliance;
- (c) Reviewing records for accuracy and completeness; and
- (d) Collecting data for reporting purposes.

(2) The VRC is responsible for the following:

1. **Scheduling.** Facilities should make every effort to give each veteran a PGR examination within 30 days of the request date. If numerous consultations are required, all of these should be scheduled on the same day, whenever possible, so that the veteran will not be unduly inconvenienced. When it is not possible to provide all consultations on the same day, the VRC/scheduler should work with the veteran to minimize disruptions in the veteran's life. If a medical center fails to meet the time standard of 30 calendar days from date of request, the medical center Director in coordination with the Regional Office Director shall work together to explore all alternatives; i.e., referrals to other VA facilities, additional staff hours to perform these examinations; and the possibility of the use of fee-basis sources or contracting out some or all examinations with volume health care providers, to bring the medical center in line with the time standard.

2. **Disseminating Information.** It is important that each Persian Gulf veteran be fully advised of the PGR examination. Facility staff are encouraged to fully communicate all aspects of the PGR examination by any appropriate means. The following alternatives might be considered:

a. Upon distribution by VA EAS, provide each Persian Gulf veteran reporting to the outpatient area, with a VHA Headquarters (131) handout, "VA Persian Gulf Veterans' Illnesses, Questions and Answers," Information Bulletin IB 10-41, describing the purpose of the examination and its limitations. This can be further clarified by the examining physician prior to and during the course of the physical examination.

b. VRCs will also provide each veteran with a brief oral explanation of the purposes of the PGR and the examination process and respond to any questions the veteran might have. This can be accomplished during the VRCs initial contact with the veteran.

c. **Computerized Record or Card File.** A computer record or card file will be established to include data on all registry participants. Each computer record or card file should include veteran's full name, address, telephone number, date of birth, Social Security Number (SSN), date of initial examination and date(s) of subsequent follow-up examination(s). *NOTE: This record will support the statistics included in the Bi-*

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monthly Report of Persian Gulf War Veteran Registry Examinations (RCS 10-0860). In addition to other information updates, every effort should be made by the VRC to maintain the veteran's current address in the computer record or card file for outreach purposes. VHA Headquarters is in the process of establishing a VA system-wide computerization of this card file.

3. Code Sheet Completion

a. The VRC, or designee, will complete Part I of VA Form 10-9009A, and will ensure that all information is entered on the code sheet before the veteran is referred to the clinician for the examination.

b. The VRP will complete Part II and III of VA Form 10-9009A. (Refer to instructions and sample code sheet in App. 2C).

c. In the event that a veteran requests a PGR examination but does not wish to be included in the registry database, a registry examination should be performed. Item 32, "Remarks," should indicate the current date and note that the veteran chose not to participate in the registry. This code sheet should be filed in veteran's CHR. Do not submit this code sheet to the AAC.

2.05 CONSOLIDATED HEALTH RECORD (CHR)

The VRC will ensure that a CHR on each registry participant is created if one does not already exist.

a. All Persian Gulf veterans participating in the registry will have a VA Form 10-9009B (Persian Gulf Identification Sticker) affixed to their CHR. VA Form 10-9009B should be affixed to the front of the record in the lower left-hand corner of the "service connected" block.

b. These Persian Gulf registry records are subject to the same retention and disposition policies as other medical record files, i.e., Records Control Schedule 10-1.

2.06 INCARCERATED VETERANS

VA medical facilities can provide assistance to penal authorities or institutions, which agree to provide examinations to veterans, without reimbursement from VA, for purposes of entry in the PGR.

a. Copies of directives, code sheets, etc., will be provided to penal institutions upon request.

b. Penal authorities must be advised at the time of such requests that the results of the examinations provided at their institutions must be returned to the VA medical facility of jurisdiction for inclusion, in the veteran's behalf, in PGR and in the veteran's CHR.

2.07 VETERANS WITH OTHER THAN HONORABLE DISCHARGES

The requirements of M-1, Part I, Chapter 4, applies to veterans with less than honorable discharges applying for PGR examinations.

2.08 ACTIVE DUTY MILITARY PERSONNEL

When active duty members of the uniformed services apply to VA facilities for a PGR examination, Department of Defense (DOD) must authorize and provide the appropriate DOD Form 2161, Referral for Civilian Care, requesting this examination or provide services under existing DOD/VA sharing agreement. The requirements of M-1, Part I, Chapter 15, regarding the authorization and billing from the appropriate branch of service will apply. Facilities should also reference the current directive providing the interagency billing rates.

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a. Procedures for processing the examination are the same as those for a veteran participating in this program.

b. A military facility may perform the PGR examination according to VA instructions or the corresponding military instructions. *NOTE: DOD has established a Persian Gulf Hot Line, telephone number 1-800-796-9699 to direct active duty personnel to military hospitals for medical examinations and provide other related information. An additional telephone number has been established (1-800-472-6719) for Persian Gulf War veterans to call with their recollection of "incidents" that might be related to health problems.*

c. Military facilities may obtain the pertinent VA administrative issue and appropriate forms from the nearest VA facility. The VA Medical Center, 50 Irving Street, N.W., Washington, DC 20422, Attn: Persian Gulf Coordinator (136), is the processing center for all active duty members of uniformed services stationed overseas. Military facilities will complete code sheets with exception of the following which will be filed in by VA coding clerks:

	<u>Blocks</u>	<u>Code Identifier</u>
<u>Part I</u>	2 to 7 137 to 141	Facility number and suffix County and State

d. Military facilities will provide completed copies of the code sheet, physical examination, laboratory tests, etc., to the nearest VA medical center or outpatient clinic. The VRC will:

(1) Prepare a colored card (or computerized facsimile) for the file with similar data as for a veteran and label the card "Active Duty";

(2) Complete the code sheet to include facility number/suffix, if applicable, county and state codes.

(3) Submit code sheet to the VA Office of Financial Management, AAC, 1615 Woodward Street, Austin, TX 78722-0001, in accordance with instructions;

(4) Establish a CHR if one does not already exist and file the PGR examination in this folder; and

(5) If requested, and only with written authorization (release of information) from active duty member, VA may supply a copy of these medical records to the military facility.

2.09 UPDATING VRP AND VRC APPOINTMENTS

Separate listings of VRPs and VRC's are maintained within EAS.

a. In an effort to keep these listings current, facilities are required to notify the EAS of any changes in the status of appointments of VRPs and/or VRC's at their respective facilities.

b. As changes in designation occur, submit in writing the name, title, mail routing symbol, FTS and commercial numbers including area code, to the VRC (103A), EAS, VA Central Office, 810 Vermont Avenue, N.W., Washington, DC 20420 (Facsimile Number FTS 700-565-7572). *NOTE: In order to provide current Persian Gulf information to concerned VA Registry Staff, it is important that any changes in designation of VRPs or VRCs at VA facilities be provided to VA Central Office (103A) as they occur.*

2.10 REPORT TO AAC

The PGR report should be prepared monthly and submitted to the AAC as per instructions contained in Appendix 2D:

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a. VA Form 10-9009A (July 1995), Persian Gulf Registry Code Sheet, and VA Form 7252, (originally 30-7252) Transmittal Form for the Use in Shipment of Tabulating Data, should be prepared monthly and submitted to AAC as per instructions contained in Appendix 2D. *NOTE: These code sheets should be submitted, based on the following schedule, but no later than 25 working days following initial examination.*

b. The schedule of mailing dates is:

- (1) Region 1 – 6th of month;
- (2) Region 2 – 10th of month;
- (3) Region 3 – 14th of month; and
- (4) Region 4 – 18th of month.

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DEFINITIONS AND ACRONYMS

1. AAC - The Office of Financial Management, Austin Automation Center (AAC) was formerly the Data Processing Center in Austin, TX. It is the location of the computerized registry for code sheet collection and database entry.
2. AMIS - Automated Management Information System.
3. ANA - Anti-Nuclear Antibody.
4. BAER - Brainstem Auditory Evoked Response.
5. CAPS-PTSD - Clinical Administered-Post Traumatic Stress Disorder.
6. CARC - Chemical Agent Resistant Compound paint.
7. CBC - Complete Blood Count.
8. CHR - Consolidated Health Record - A file containing medical records relating to patient identity, diagnosis, prognosis or treatment at VA facility.
9. CPK - Creatine Phosphokinase.
10. CT - Computed Tomography.
11. D.O. - Doctor of Osteopathy.
12. DOD - Department of Defense.
13. DOD Form 2161, "Referral for Civilian Care."
14. DSM-III-R - Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised.
15. DU - Depleted Uranium.
16. EAS - Environmental Agents Service - EAS (103A), VA Central Office, has the responsibility to coordinate and monitor all VHA activities, research and otherwise, relating to the Persian Gulf issue.
17. ECG - Electrocardiogram.
18. EEG - Electroencephalogram.
19. EGD - Esophagastroduodenoscopy.
20. EMG - Electromyogram.
21. ENG - Electronystamogram.
22. Examinations
 - a. Initial: The first physical examination which is completed and sent to the AAC for the purpose of entering a veteran into the Persian Gulf Registry system.

- b. Follow-up - Examination performed subsequent to the initial (first) examination.
- 23. Facility - Any VA facility which provides Persian Gulf Registry examinations to Persian Gulf veterans.
- 24. GI - Gastrointestinal.
- 25. GYN - Gynecology.
- 26. HcT - Hematocrit.
- 27. HgB - Hemoglobin.
- 28. HIV - Human Immuno-deficiency.
- 29. IB-10-41 - VA Information Bulletin entitled "Persian Gulf Veterans' Illnesses, Questions and Answers."
- 30. ICD-9-CM - The International Classification of Diseases, Clinical Modification, 9th Edition provides standardized classification of diseases.
- 31. IgG - Oligoclonal.
- 32. KIA - Killed in Action.
- 33. KTO - Kuwait Theater of Operations.
- 34. LDH - Lactic Acid Dehydrogenase.
- 35. LP - Lumbar Puncture.
- 36. MAS - Medical Administration Service.
- 37. MIA - Missing in Action.
- 38. MOS - Military Occupational Specialty.
- 39. M.D. - Doctor of Medicine.
- 40. MRI - Magnetic Resonance Imaging.
- 41. MSLT - Multiple Sleep Latency Test.
- 42. NCV - Nerve Conduction Velocity.
- 43. O&P - Ova and Parasites.
- 44. P.A. - Physician's Assistant.
- 45. PFT - Pulmonary Function Test.
- 46. PGR - Persian Gulf Registry - The PGR is a computerized index of veteran participants, is managed centrally by the EAS in VA Central Office. The coded findings of Persian Gulf Program physical examinations and related diagnostic results are entered into a database by the AAC.
- 47. PGRC - Persian Gulf Referral Centers - Selected tertiary VA Medical Centers (Birmingham, AL, Houston, TX; , Washington, DC; and West Los Angeles, CA), with clinical and academic expertise in such areas as

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pulmonary and infectious diseases, immunology, neuropsychology, and toxicology, where medical assistance is provided for those Persian Gulf veterans with symptoms which defy explanation.

48. Plt - Platelet.

49. PPD - Purified Protein Derivative.

50. PTF - Patient Treatment File.

51. PTSD - Post Traumatic Stress Disorder.

52. Persian Gulf Area of Service. For eligibility purposes, active military duty in Southwest Asia during the Persian Gulf War would include service in one or more of the following areas: Iraq, Kuwait, Saudi Arabia, the neutral zone (between Iraq and Saudi Arabia), Bahrain, Qatar, the United Arab Emirates, Oman, waters of the Persian Gulf, Red Sea, Arabia Sea, and Gulfs of Aden and Oman.

53. Persian Gulf War Period of Service. Public Law 102-25 established a Persian Gulf War period of service which will affect persons serving on active duty as of August 2, 1990, with no ending date established by law.

54. Records Control Schedule (RCS) 10-1. Provides instructions for record retention and disposition.

55. Reports Control System (RCS) 10-0860. This RCS number (In new documents this RCS number has been replaced by the Records Control Number (RCN)) reflects the reporting requirements for the following:

- a. VA Form 10-9009, Persian Gulf Registry Code Sheet,
- b. VA Form 10-9009c, Persian Gulf Registry Code Sheet (Spouse or Child of Persian Gulf Veteran).
- c. Persian Gulf Referral Center Monthly Report.
- d. Bi-monthly Report on Persian Gulf Uniform Case Assessment Protocol.
- e. Bi-monthly Report on Persian Gulf War Veteran Registry Examinations.

56. RCS 10-0875. This RCS number has been replaced by RCS 10-0860.

57. RHP - Reproductive Health Problems.

58. SCID - Structured Clinical Interview for DSM-III.

59. SCUDS - Soviet designed surface to surface missiles.

60. SED - Skin Erythema Dose.

61. SGPT(ALT) - Transaminase Glutamic Pyruvate.

62. SGOT(AST) - Glutamic Oxaloacetic Transaminase.

63. SMA (6/12) - SMA is a Manufacturer's Trademark for a Chemistry Analyzer.

64. SSN - Social Security Number.

65. T4 - Thyroxine Total Serum.

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- 66. TB - Tuberculosis.
- 67. TSH -Thyroid Stimulating Hormone.
- 68. UCAP- Uniform Case Assessment Protocol.
- 69. UGI- Upper Gastrointestinal.
- 70. VA - Department of Veterans Affairs.
- 71. VBC -Veterans Benefits Counselor.
- 72. VDRL - Venereal Disease Research Laboratory.
- 73. VHA - Veterans Health Administration.
- 74. VRC - Veterans' Registry Coordinator - A non-physician staff member responsible for the administrative management of the program at each VA facility.
- 75. VRP - Veterans' Registry Physician - The VRP is a physician responsible for the clinical management of the Persian Gulf Program at each VA medical facility.
- 76. VA Form 10-60098 - Identification Sticker entitled "Persian Gulf."
- 77. VA Form 30-7252 changed to VA Form 7252, Transmittal Form for Use in Shipment of Tabulating Data.
- 78. WBC - White Blood Cells.

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PROTOCOL FOR CONDUCTING THE PHYSICAL EXAMINATION AND ORDERING DIAGNOSTIC STUDIES

1. It is essential that a complete medical history, physical examination and interview be performed and documented on appropriate forms. The required forms that must be fully completed are: Standard Form (SF) 88, Report of Medical Examination, Department of Veterans Affairs (VA) Form 10-9009A, Persian Gulf Registry Code Sheet, and SF 509, Progress Notes (for follow-up). These are to be maintained in the veteran's Consolidated Health Record (CHR). *NOTE: This should be accomplished by or under the direct supervision of the Veterans' Registry Physician (VRP). Examination data will be recorded in the veteran's medical record as routinely as done for any other medical examination. The complete medical history should address the following:*

- (a) Family history;
- (b) Occupational history;
- (c) Social history including tobacco, alcohol, drug use;
- (d) Civilian exposure(s) history to possible toxic agents;
- (e) Psychosocial history; and
- (f) Review of systems.

2. The person actually performing the physical examination will be identified by name, signature and title (i.e., Doctor of Osteopathy, Doctor of Medicine, Physician's Assistant, etc.). A physician's countersignature is required if the examiner is other than a physician. Under normal circumstances, VRP will provide such countersignatures.

3. When a Persian Gulf Registry (PGR) examination is done as part of a compensation and pension examination, the physical examination will be done by/for under the direct supervision of the VRP.

4. The physician should be aware of the variety of exposures endemic to the Persian Gulf area. These are listed in Appendix 2C and on VA Form 10-9009A. There has been a wide distribution of major categories of diagnosis reported by VA VRPs; however, no significant variation in occurrence of major categories of medical problems has been identified. We are listing below (for informational purposes) some of the health problems and/or diseases which should be considered:

NOTE: Unfortunately the International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM) coding system does not give sufficient codes to correctly identify all symptoms and diagnoses. A number of diagnoses that have been reported by Veterans Registry Physicians do not have ICD-9-CM codes for specific identification in the Veterans Health Administration (VHA)'s database. To correct this, three new codes have been created. They are: Apnea, Sleep (99001), Chronic Fatigue Syndrome (CFS) (99002), and Fibromyalgia (99003). Make certain these codes are used when completing the Persian Gulf Registry code sheets for patients who have these diagnoses. As a result of inadequate coding designations, there has been confusion between the symptoms (complaints) and diagnoses listed on the PGR code sheets. Example one: Arthralgia (diagnostic code 7194) has been used for the symptom "pain in the joint," where the symptom code 7819 (other symptoms involving nervous and musculoskeletal systems) would be more appropriate. Example two: Symptom ICD-9-CM code 78051 has been designated for insomnia with sleep apnea; however, sleep apnea is more correctly identified as a specific diagnosis which has the new code 99001. Symptom code 78051 may still be used for insomnia with sleep apnea. Example three: Symptom ICD-9-CM code 7807 has been used to designate CFS and the symptoms of malaise and fatigue. The new code 99002 has been determined for CFS, so ICD-9-CM code 7807 should be used for medical complaints of malaise and fatigue

<u>DIAGNOSIS</u>	<u>International Classification of Diseases</u> <u>ICD-9-CM Code</u>
(1) Amebiasis	006
(2) Apnea, sleep	99001
(3) Arthralgia	7194
(4) Asthma	493
(5) Brill's Zinsser disease (recrudescence typhus)	0811
(6) Bronchiectasis	494
(7) Bronchopneumonia, organism unspecified	485
(8) Brucellosis	023
(8) Chronic obstructive pulmonary disease, not elsewhere classified	496
(9) Chronic bronchitis	491
(10) Chronic Fatigue Syndrome	99002
(11) Chronic Laryngotracheitis	4761
(12) Chronic respiratory conditions due to fumes and vapors	5064
(13) Emphysema	492
(14) Fibromyalgia	99003
(15) Giardiasis	0071
(16) Leishmaniasis	085
(17) Malaria	084
(18) Other and unspecified diseases of upper respiratory tract	4789
(19) Pneumoconiosis due to other silica or silicates	502
(20) Pneumoconiosis, unspecified	505
(21) Unspecified chronic respiratory disease	5199
(22) Respiratory conditions due to unspecified external agent	5089
(23) Sandfly fever (phlebotomus fever)	0660
(24) Schistosomiasis (bilharziasis)	120
(25) Toxoplasmosis	130

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<u>DIAGNOSIS</u>	<u>ICD-9-CM Code</u>
(26) Typhoid fever, also carrier - V02.1	0020
(27) Tuberculosis, specify variant(s)	010-018
(28) Viral hepatitis	070
(29) Memory loss	310
(30) Polyneuropathy	356-357
(31) Skin rash	680-709
(32) Adjustment disorder, including Post Traumatic Stress Disorder (PTSD)	309
(33) Alcohol dependence syndrome	303
(34) Drug dependence	304

5. In gathering these data, it is important to determine and record, the:

- a. Time of onset of the symptoms or conditions,
- b. Intensity,
- c. Degree of physical incapacitation, and
- d. Details of any treatment received.

6. Each veteran will be given the following baseline laboratory studies (Phase I Registry Examination):

- a. Complete Blood Count (CBC);
- b. Electrolyte Glucose (SMA-6, SMA-12), or equivalent blood chemistries and enzyme studies; and
- c. Urinalysis.

7. Appropriate additional diagnostic studies should be performed and consultations obtained as indicated by the patient's symptoms and the physical and laboratory findings. *NOTE: If individuals have unexplained illnesses, after a Phase I registry examination is performed, a Phase II examination is mandated. (See Ch. 3, App 3A, for instructions.)*

a. Other diagnostic studies, such as pulmonary function test, sperm counts, should be performed if medically indicated.

- b. Laboratory tests results should be filed in the CHR.

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**SAMPLE AND INSTRUCTIONS FOR COMPLETING
 VA FORM 10-9009A (JULY 1995), PERSIAN GULF REGISTRY CODE SHEET, PHASE I**

1. General Instructions for completing Department of Veterans Affairs (VA) Form 10-9009A (July 1995).

a. An original code sheet should be prepared and a legible copy submitted to the Office of Financial Management Austin Automation Center (AAC) in accordance with instructions for the initial and first follow-up examinations (if required). After code sheet data has been reviewed and entered into the computerized database at AAC, the AAC will forward these code sheets to the Senior Registry Coordinator (103A), Department of Veterans Affairs, 810 Vermont Avenue, N.W., Washington, DC 20420, for disposition. These code sheets will not be returned to the medical center of origin unless corrections are required.

(1) The original code sheet will be filed in the medical record with any corrections required by AAC. Additional follow-up examinations, as required, will continue to be documented in the Consolidated Health Record (CHR).

(2) A code sheet for additional follow-up examinations will not be prepared or submitted to the AAC with the exception that if a diagnostic code differs from previously submitted code sheets, then a code sheet will be prepared and submitted for entry into the Persian Gulf Registry (PGR).

b. Print clearly using a BLACK ball-point pen or a BLACK felt-tipped pen. Follow instructions carefully to ensure that all data fields are accurately completed. Enter one letter or number per block. The numeric zero must be slashed "0." For registry coding purposes, use the International Classification of Diseases - Clinical Modification, 9th Edition, (ICD-9-CM) codes. These must be the codes currently in use by AAC.

(1) Part I of the code sheet should be completed in the presence of the veteran.

(2) Parts II and III of the code sheet should be completed at the time of the examination by the Veterans' Registry Physician (VRP). A completed Parts II and III will be returned to Medical Administration Service (MAS) for assignment of the ICD-9-CM codes in appropriate blocks. *NOTE: Careful attention should be paid to assigning the correct code for both complaints (symptoms) and diagnosis. ICD-9-CM code 78999, for uncodable complaints (symptoms), should be assigned only after all coding possibilities have been thoroughly explored. The indiscriminate use of ICD-9-CM code 78999 may result in skewed or misleading statistics of minimal value.*

(3) Date all code sheets with current date in the upper right hand corner of VA Form 10-9009A (July 1995).

2. Instructions for Completing Part I (Initial Examination)

a. Item 1. Blocks 2-7. Facility Number and Suffix. Enter facility code as listed in MP-6, Part XVI, Supplement No. 4.1, Appendix A. Use the AMIS suffix (BY, BZ, etc.) to indicate your satellite facility. DO NOT USE Q, R, OR S. *NOTE: If veteran requests the inclusion of his Department of Defense (DOD) registry examination records in VA PGR, submit code sheet with Facility Number as 999 in Blocks 2, 3 & 4 and indicate actual VA facility number in upper left margin of codesheet.*

b. Item 2. Blocks 8-33. Last Name of Veteran. Beginning in Block 8, enter veteran's current last name. If veteran had an earlier last name used during the veteran's Persian Gulf service, e.g., an unmarried woman, leave one space blank after the current name and enter "E." If veteran has had any other later name, leave another blank space (i.e., after "E"), and enter the later name followed by another

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blank space and then enter "L." Do not use apostrophe and/or hyphen in the name or skip blocks between the letters of the last name. Skip a block if the last name is followed with Jr., Sr., I, II, III, etc.

c. Item 3. Blocks 34-48. First Name of Veteran. Beginning in Block 34, enter veteran's first name.

d. Item 4. Blocks 49-58. Middle Name of Veteran. Beginning in Block 49, enter veteran's middle name or initial.

e. Item 5. Block 59. Type of Examination. The following transaction type must be entered in Block 59 as appropriate:

A - Initial examination. Veteran's first Persian Gulf examination.

B - To delete an entire initial examination with a noted error, after it has been accepted into the registry, resubmit the original code sheet with a "B" and submit another code sheet with the correct information with an "A." All fields must be completed on a resubmission. The code sheets can be submitted in the same batch. Examples of this usage are incorrect diagnosis, military statistics, Social Security Number (SSN), etc.

C - Follow-up examination. Veteran's second Persian Gulf examination. Additional follow-up examinations, as required, will continue to be documented in the CHR, but a code sheet will not be prepared or submitted to the AAC with the following exception: if a diagnostic code differs from previously submitted code sheets, then a code sheet should be prepared and submitted for entry into the PGR.

D - To delete an entire follow-up PGR examination with a noted error, after it has been accepted into the registry, resubmit the original code sheet with a "D" and submit another code sheet with the correct information with a "C."

E - To submit change in demographics, i.e., change of address or date of birth enter "E" and complete items with name, SSN, date of birth, and address. No other items need to be completed.

I - To include those veterans whose names are not on the PGR but would like their name and address included on a mailing list for the "Persian Gulf Review" newsletter.

X - When a registry participant has been identified and verified as being deceased, enter "X." Complete items with name, SSN, and date of birth. No other items need to be completed.

f. Item 6. Blocks 60-69. SSN. Shaded Block 60 is to be used ONLY if a pseudo SSN is being submitted. In this event, the letter "P" will be entered in Block 60. Leave Block 60 blank when the actual SSN is used. Beginning in Block 61 enter the veteran's actual SSN, or pseudo SSN. (See M-1, Part I, Ch. 5, Par. 5.29, for instructions on pseudo SSN assignment.) NOTE: *All efforts should be made to obtain veteran's actual SSN.*

g. Item 7. Blocks 70-75. Date of Birth. Beginning in Block 70 enter numerical equivalent for the month, day and year in that order (e.g., 01/19/50). All blocks must be completed.

h. Item 8. Blocks 76-141. Permanent address.

(1) Blocks 76-101. Beginning in Block 76 enter veteran's permanent street address.

(2) Blocks 102-127. Beginning in block 102 enter veteran's city or town.

(3) Blocks 128-132. Enter zip code of permanent residence (National Zip Code Directory).

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- (4) Blocks 133-136. Leave Blank (future extended Zip Code).
- (5) Blocks 137-139. Enter appropriate county code as listed in M-1, Part I, Chapter 18, Appendix A.
- (6) Blocks 140-141. Enter appropriate state code as listed in M-1, Part I, Chapter 18, Appendix A.

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I. Item 9. Block 142. Race/Ethnicity. Enter one of the following codes in Block 142:

- 1 = American Indian or Alaskan Native
- 2 = Asian or Pacific Islander
- 3 = Black, not of Hispanic Origin
- 4 = White, not of Hispanic Origin
- 5 = Hispanic
- 6 = Unknown

J. Item 10. Block 143. Marital Status. Enter one of the following codes in Block 143:

- 1 = Married
- 2 = Divorced
- 3 = Separated
- 4 = Widowed
- 5 = Single, Never Married

K. Item 11. Block 144. Sex. Enter one of the following codes in Block 144:

- M = Male
- F = Female

L. Item 12. Block 145. Current Status. Enter one of the following codes in Block 145:

- 1 = Inpatient
- 2 = Outpatient
- 3 = Incarcerated
- 4 = Active Duty (Outpatient)
- 5 = Active Duty (Inpatient)

M. Item 13. Block 146. Branch of Service. If veteran was in more than one branch of service, code the latest Persian Gulf service. Enter one of the following codes in Block 146:

- 1 = Army (Including Reserves & National Guard)
- 2 = Air Force (Including Reserves & National Guard)
- 3 = Navy (Including Reserves)
- 4 = Marine Corps
- 5 = Coast Guard
- 6 = Other (e.g., Public Health Service, National Oceanic and Atmospheric Administration)

N. Item 14, 14A and 14B. Blocks 147-163. Military Service in Persian Gulf.

(1) Block 147. Enter one of the following codes:

Y = Yes (If yes, list the dates of veterans last two periods of service in Persian Gulf.)

N = No (If the veteran did not serve in Persian Gulf, the veteran is not eligible for a Persian Gulf Registry examination.)

(2) Item 14A. Enter the numerical equivalent of the month and also two digits of the year of last period of service in Persian Gulf (e.g., from 02/91 to 05/91) in Blocks 148 through 155.

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(3) Item 14B. If veteran had two or more periods of service in Persian Gulf, the longest period of service should be entered in Blocks 156 through 163. If only one period of service in Persian Gulf, enter in 14A and leave 14B blank.

a. Item 15, 15A and 15B. Blocks 164-165. In What Area(s) Did Veteran Serve?

(1) Item 15A. Block 164. Enter one of the following codes:

- 1 = Combat Zone
- 2 = Other Land Area
- 3 = Sea Duty

(2) Item 15B. Block 165. If other service is indicated or, if the response is "Don't Know" enter appropriate code in Block 165.

- 4 = Other (Specify i.e., Air Force: Ground or Air Crew, etc.)
- 5 = Don't Know

p. Item 16, 16A-16E. Military Units, MOS and Block 166. MOS-Different Duties.

(1) Item 16A. Military Units. Enter the military unit in which the veteran served. Specify complete unabbreviated title, that is, company, battalion, corps, ship, division, etc., (e.g., Company C, 1st Battalion, 4th Army).

(2) Item 16B. Military Occupational Specialty (MOS): Enter the veteran's MOS.

(3) Item 16C. Block 166. Were actual duties different from MOS? Enter one of the following codes in Block 166: If no, go to Item 16E

- Y = Yes
- N = No

(4) Item 16D. If yes, enter actual duties which were different from MOS on code sheet and in CHR.

(5) Item 16E. Enter the name of unit with which the veteran had the longest and next to longest period of service while in the Persian Gulf.

NOTE: Items 16A & 16E: These units could be different from the one to which the veteran was assigned if the veteran was on detached duty.

q. Items 17, 17A and 17B. Blocks 167-182. Last two periods of service (If different from 14A and 14B). Enter the numerical equivalent of the month and the last two digits of the year for the last two periods of service regardless of whether or not they were in the Persian Gulf (e.g., from 12/90 to 04/91 and 9/90 to 11/90). If veteran did not have more than one period of service, leave blank. For active duty military personnel, enter date when service began (e.g., 12/90) and enter nines (e.g., 99/99) to indicate the veteran is still actively serving in the military.

r. Items 18, 18A-1821. Blocks 183-216. Veteran's Exposure to Environmental Factors. Enter the following codes in appropriate blocks.

- Y = Yes
- N = No

(1) Item 18A. Block 183. Are you currently smoking cigarettes? If no, go to Item 18D.

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(2) Item 18B. Blocks 184-185. If yes, how many years have you been smoking cigarettes? Enter number of years.

(3) Item 18C. Blocks 186-187. If yes, on the average, how many packs are you smoking per day?

(4) Item 18D. Block 188. Have you smoked cigarettes in the past? If no, go to Item 18G.

(5) Item 18E. Blocks 189-190. If yes, how many years did you smoke?

(6) Item 18F. Blocks 191-192. If yes, on the average how many packs did you smoke per day?

(7) Item 18G-Z1. Blocks 193-212. While in the Persian Gulf do you believe you were exposed to any of the following? Enter the following codes:

Y = Yes

N = No

U = Unknown

(8) Item 18G. Block 193. Smoke from oil fires?

(9) Item 18H. Block 194. Smoke or fumes from tent heaters?

(10) Item 18I. Block 195. Cigarette Smoke (passive) from others?

(11) Item 18J. Block 196. Diesel and/or other petrochemical fumes?

(12) Item 18K. Block 197. Exposure to burning trash/feces?

(13) Item 18L. Block 198. Skin exposure to diesel or other petrochemical fumes?

(14) Item 18M. Block 199. Chemical Agent Resistant Compound (CARC) paint?

(15) Item 18N. Block 200. Other paints and/or solvents and/or petrochemical substances?

(16) Item 18O. Block 201. Depleted uranium?

(17) Item 18P. Block 202. Microwaves?

(18) Item 18Q. Block 203. Personal pesticide use, including creams, sprays, or flea collars?

(19) Item 18R. Block 204. Nerve gas or other nerve agents?

(20) Item 18S. Block 205. Drug (pyridostigmine) used to protect against nerve agents?

(21) Item 18T. Block 206. Mustard gas or other nerve agents?

(22) Item 18U. Block 207. Ate or drank food contaminated with smoke, oil or other chemical?

(23) Item 18V. Block 208. Ate food other than provided by Armed Forces?

(24) Item 18W. Block 209. Bathed in or drank water contaminated with smoke, oil or other chemical?

(25) Item 18X. Block 210. Bathed in water other than provided by Armed Forces?

(26) Item 18Y. Block 211. Immunization against anthrax?

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(27) Item 18Z. Block 212. Immunization against botulism?

(28) Item 18Z1. Other exposures? Enter on code sheet and in CHR.

a. Items 18A-F. Blocks 213-218 Persian Gulf Experience. Did you have any of the following experiences while in the Persian Gulf?

(1) Item 18A. Block 213. Did you ever go on combat patrols or have other very dangerous duty? Enter the following codes:

- 1 = No
- 2 = 1-3X
- 3 = 4-12X
- 4 = 13-50X
- 5 = 51+times

(2) Item 18B. Block 214. Were you ever under enemy fire, including, Soviet designed surface to surface missiles (SCUDS)? Enter the following codes:

- 1 = Never
- 2 = less than 1 day
- 3 = less than 1 week
- 4 = 1-4 weeks
- 5 = 4 weeks or more

(3) Item 18C. Block 215. What percentage of people in your unit (your immediate group) were Killed in Action (KIA), wounded or Missing in Action (MIA)? Enter the following codes:

- 1 = None
- 2 = 1-25%
- 3 = 26-50%
- 4 = 51-75%
- 5 = 76% or more

(4) Item 18D. Block 216. How often did you see someone hit by incoming or outgoing rounds? Enter the following codes:

- 1 = Never
- 2 = 1-2X
- 3 = 3-12X
- 4 = 13-50X
- 5 = 51 or more

(5) Item 18E. Block 217. How often were you in danger of being injured or killed (i.e., pinned down, overrun, ambushed, near miss, etc.)? Enter the following codes:

- 1 = Never
- 2 = 1-2X
- 3 = 3-12X
- 4 = 13-50X
- 5 = 51 or more

(6) Item 18F. Block 218. Witnessed chemical alarms? Enter the following codes:

- Y = Yes
- N = No

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U = Unknown

L. Item 20. Block 219. Veteran's Health (Veteran's evaluation).

(1) Item 20A. Enter one of the following codes which best describes veteran's health after Persian Gulf Service:

- 1 = Very good
- 2 = Good
- 3 = Fair
- 4 = Poor
- 5 = Very poor

u. Item 21. Block 220. Veteran's Functional Impairment.

(1) Item 21A. Enter code which describes veteran's assessment of the veteran's functional impairment, after Persian Gulf Service, using the following scale:

- 1 = No impairment
- 2 = Slight impairment
- 3 = Moderate impairment
- 4 = Severe impairment

(2) Item 21B. Blocks 221-222. How many workdays were lost by veteran due to illness in the past 90 days? Enter number of days lost in Blocks 221-222 (e.g., 8/2). If none fill in the blocks with 0s. If the veteran does not work outside the home, annotate this information in Item 32, Remarks.

v. Item 22. Blocks 223-262. Evidence of Birth Defects and Infant Death(s) among veteran's children and problems with pregnancy and infertility. NOTE: Where blanks are indicated complete blocks with 0s.

(1) Item 22A. Blocks 223-224. How many children does the veteran have? If none, enter 0s, and go to 22C.

(2) Item 22B. Blocks 225-226. Birth Defects. NOTE: Birth defects are any structural, functional, or biochemical abnormality at birth whether genetically determined or induced during gestation that is not due to injuries suffered during birth. How many of these children were born with birth defects? Enter number of children in Blocks 225-226. If none, go to Item 22C.

(a) Item 22B1. Blocks 227-228. How many of these children were conceived before Gulf service? If none, enter 0s, and go to Item 22B2.

(b) Item 22B1(a). Blocks 229-230. State maternal age at conception of first child conceived before Gulf service. Enter age in Blocks 229-230.

(c) Item 22B2. Blocks 231-232. How many children were conceived during or after Gulf service? Enter number in Blocks 231-232. If none, enter 0s, and go to Item 22C.

(d) Item 22B2(a) Blocks 233-234. State maternal age at conception of first child conceived during or after Persian Gulf service? Enter age in Blocks 233-234.

(3) Item 22C. Blocks 235-241. Infertility (Problems of veteran or spouse becoming pregnant). NOTE: Infertility—relative sterility defined as inability to conceive after 12 or more months of intercourse without use of contraception when neither spouse is surgically sterilized. Has veteran or spouse had infertility problems? Enter one of the following codes in Block 235. If none, go to Item 22D.

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Y = Yes
N = No

(a) Item 22C1. Block 236. Has veteran or spouse had infertility before Gulf service? Enter one of the following codes:

Y = Yes
N = No

If no, go to Item 22C2.

(b) Item 22C1(a). Blocks 237-238. State maternal age during first attempts to conceive. Enter age in Blocks 237-238.

(c) Item 22C2. Block 239. Has veteran or spouse had infertility after return from Gulf service? Enter one of the following codes.

Y = Yes
N = No

If no, go to Item 22D.

(d) Item 22C2(a). Blocks 240-241. State maternal age during first attempts to conceive. Enter age in Blocks 240-241.

(4). Item 22D. Blocks 242-248. Miscarriage(s). *NOTE: Miscarriages are spontaneous expulsion of the products of conception before 20 weeks of gestation (spontaneous abortion).* Has veteran or spouse had miscarriage(s)? Enter one of the following codes in Block 242.

Y = Yes
N = No

If no, go to Item 22E.

(a) Item 22D1. Block 243. If yes, has veteran or spouse had miscarriage(s) before Gulf service? Enter one of the following codes:

Y = Yes
N = No

If no, go to Item 22D2.

(b) Item 22D1(a). Blocks 244-245. State maternal age at conception. Enter age in Blocks 244-245.

(c) Item 22D2. Block 246. Has veteran or spouse had miscarriage(s) after return from Gulf service? Enter one of the following codes:

Y = Yes
N = No

If no, go to Item 22E.

(d) Item 22D2(a). Blocks 247-248. State maternal age at conception. Enter age in Blocks 247-248.

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(5) Item 22E. Blocks 249-255. Still Birth(s). *NOTE: Still births are births after 20 weeks of gestation of an infant who showed no evidence of life after birth.* Has veteran or spouse had still birth(s)? Enter one of the following codes in Block 249:

Y = Yes
 N = No

If no, go to Item 22F.

(a) Item 22E1. Block 250. Has veteran or spouse had still birth(s) before Persian Gulf service? Enter one of the following codes in Block 250.

Y = Yes
 N = No

If no, go to Item 22E2.

(b) Item 22E1(a). Blocks 251-252. State maternal age at conception. Enter age in Blocks 251-252.

(c) Item 22E2. Block 253. Has veteran or spouse had still birth(s) after return from Persian Gulf service? Enter one of the following codes in Block 253:

Y = Yes
 N = No

If no, go to Item 22F.

(d) Item 22E2(a). Blocks 254-255. State maternal age at conception. Enter age in Blocks 253-254.

(6) Item 22F. Blocks 256-262. Infant Death(s). *NOTE: Death that occurred within 1 year of birth among babies born alive.* Has veteran or spouse had babies with infant death(s)? Enter one of the following codes in Block 256:

Y = Yes
 N = No

If no, go to Item 22G.

(a) Item 22F1. Block 257. Has veteran or spouse had babies with infant death(s) before Gulf service? Enter one of the following codes in Block 257:

Y = Yes
 N = No

If no, go to Item 22F2.

(b) Item 22F1(a). Blocks 258-259. State maternal age at conception. Enter age in Blocks 258-259.

(c) Item 22F2. Block 260. Has veteran or spouse had babies with infant death(s) after return from Gulf service? Enter one of the following code in Block 260: If no, go to Item 22G.

Y = Yes
 N = No

(d) Item 22F2(a) Blocks 261-262. State maternal age at conception. Enter age in Blocks 261-262.

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(7) Item 22G. If a woman veteran reports she was pregnant in the Persian Gulf, record the date of child's birth and hospital of birth on code sheet and in the veteran's CHR to facilitate follow-up, if needed.

3. Instructions for Completing PGR Code Sheet, Part II (Initial Examination). *To be completed by the examining physician)*

a. Item 23. Blocks 263-270. Date of Examination. Enter the numerical equivalent for the month, day, and year in that order (e.g., 09/22/1992).

b. Item 24. Blocks 271-272. Total Number of Veteran's Complaints.

c. Item 25, 25A-M. Blocks 273-417. Veteran's Complaints, Month and Year of Onset, Duration in Months, Whether Symptom is Currently Present, and Most Severe Complaint.

(1) Item 25A-J. Blocks 273-417. Columns: (1) Veteran's Complaints/Symptoms; (2) ICD-9-CM codes; (3) Month and Year of Onset; (4) Duration in months; and (5) State whether symptom is still present. List up to ten major and current symptoms/complaints. If veteran has more than 10, enter most severe. Any additional symptoms should be listed in CHRL. *NOTE: MAS coders, use ICD-9-CM "Symptom" codes in first five numbered blocks of each line. For uncodable symptoms use "78999." For no known complaints, use "78000." (All zeros are to be slashed.) However, ICD-9 code 78999 should ONLY be used if all possible codes have been reviewed, and if necessary, seek physician consultation to make a correct choice.*

(2) Item 25A-J(1). Give a narrative description of ten major, current symptoms as stated by veteran.

(3) Item 25A-J(2). Blocks 273-322. MAS coders are to complete the ICD-9-CM codes as they relate to each symptom.

(4) Item 25A-J(3). Blocks 323-382. For each symptom listed in 25A-J, state month and year of onset.

(5) Item 25A-J(4). Blocks 383-402. For each symptom listed in 25A-J, state duration in months that veteran has been experiencing this symptom.

(6) Item 25A-J(5). Blocks 403-412. For each symptom listed in 25A-J, indicate if symptom is currently present, using one of the following codes:

Y = Yes

N = No

(7) Item 25K. Block 413-417. Most Severe Symptom/Complaint. List ICD-9-CM code for most severe symptom (A symptom from Item A-J, which VETERAN considers the most severe; i.e., Chief Complaint).

d. Item 26, A-S. Blocks 418-435. Diagnostic workup/consultation. Enter one of the following codes in Blocks 418-435. All blocks must be completed.

- 1 = No workup. No consultation done.
- 2 = Workup/consultation done. Unexplained illness.
- 3 = Workup/consultation done. Diagnosis established.
- 4 = Workup/consultation done. No diagnosis.

(1) Item 26A. Block 418. Allergy/Immunology.

(2) Item 26B. Block 419. Audiology.

(3) Item 26C. Block 420. Cardiology.

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- (4) Item 26D. Block 421. Dentistry.
- (5) Item 26E. Block 422. Dermatology.
- (6) Item 26F. Block 423. Ear, Nose and Throat.
- (7) Item 26G. Block 424. Endocrinology.
- (8) Item 26H. Block 425. Gastroenterology.
- (9) Item 26I. Block 426. Hematology/Oncology.
- (10) Item 26J. Block 427. Infectious Diseases/Parasitology.
- (11) Item 26K. Block 428. Nephrology.
- (12) Item 26L. Block 429. Neurology.
- (13) Item 26M. Block 430. Occupational Medicine.
- (14) Item 26N. Block 431. Pulmonary.
- (15) Item 26O. Block 432. Psychiatry.
- (16) Item 26P. Block 433. Psychology/Psychometric Testing.
- (17) Item 26Q. Block 434. Rheumatology.
- (18) Item 26R. Block 435. Other. Were any additional workups/consultations performed as part of Persian Gulf examination which were not listed in Items 26A-Q. Enter one of the following codes:

Y = Yes
 N = No

- (19) Item 26S. Specify on code sheet and CHR any additional workups/consultations performed as part of Persian Gulf examination, which were not listed in Item 26A-Q.

e. Item 27, 27A-B. Blocks 436-485. Diagnoses.

(1) Item 27A. List up to ten major definite medical diagnoses on lines 27A-J. The examining physician will select the 10 most significant/serious in the examining physician's opinion, listing the primary diagnosis in Item A. The additional diagnosis(es) should be included in patient's CHR. Blocks 436-485 are to be used for ICD-9-CM coding of each diagnosis listed. Leave blank if no diagnosis is made. *NOTE: Diagnostic coding assignment will be completed by MAS. DO NOT REPEAT OR LIST SYMPTOM CODE ALREADY LISTED UNDER ITEM 25A-J.*

f. Item 28. Block 486. No Diagnosis Made. If no diagnosis is made, enter a "1" in Block 486; otherwise, leave this block blank. This item must be considered in conjunction with Item 27, "Diagnoses." A "1" should be entered for Item 28 only when no diagnosis is given in Item 27 indicating that no significant defect, disease, injury or history of a relevant diagnosis in the past is detected.

g. Item 29, 29A-F. Blocks 487-494. Disposition. Enter one of the following codes in Block 487-494.

Y = Yes
 N = No

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- (1) Item 29A. Block 487. Examination completed?
- (2) Item 29B. Block 488. Hospitalized at the VAMC for further tests?
- (3) Item 29C. Block 489. Hospitalized at the VAMC for treatment?
- (4) Item 29D. Block 490. Referred for outpatient care?
- (5) Item 29E. Block 491. Referred to private physician, non-VA clinic or non-VA hospital?
- (6) Item 29F. Block 492. Biopsy?

h. Item 30. Block 493. Phase I examination, refer to paragraph 5, has been completed and the physician has determined that veteran has unexplained illness. Enter one of the following codes:

Y = Yes
N = No

l. Item 31. Block 494. Has Phase II examination (refer to Ch. 3) been initiated? Enter the following codes:

Y = Yes
N = No

j. Item 32. Remarks. Utilize this section for any additional information (e.g., see par. 1.07).

k. Item 33. Name of Examiner. Print full name.

l. Item 34. Title of Examiner. Full title of Examiner.

m. Item 35. Signature of Examiner. Signature of examiner.

n. Item 35a. Signature of Physician. Signature of VRP.

4. Follow-up Examinations. Instructions for completing Parts I and II. In addition to initial registry submissions, VA Form 10-9009A, Parts I, II and III (if applicable) will be completed in reporting the first follow-up examination, and subsequent follow-up examinations if diagnostic code is different from previous examinations as follows:

- a. Items 1-12 must be completed - Control Data.
- b. Items 13-22 require no entry, unless you have follow-up data to report in any of these items.
- c. Items 23 must be completed.
- d. Items 25-26 may be blank unless you have follow-up data to report in any of these items.
- e. Item 27-35 must be completed.

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SAMPLE OF COMPLETED VA FORM 10-9009A (JULY 1995), PART I, II & III

Department of Veterans Affairs		1. Use PTF Number Only		FACILITY NO.		SUPPLY	
PERSIAN GULF REGISTRY CODE SHEET		1		543			
PART I Phase 1							
The information the member supplies may be distributed outside the VA as follows: Data and basic personal information and Personal Health Organization is used in the development of programs for research purposes and other uses as noted in the "Privacy of Systems of the National" published in the Federal Register Supplementary with the Privacy act of 1974.							
INSTRUCTIONS: Please print. Use only one name or number per block. If possible use block boldface or boldface print. Number codes for VA use only. DO NOT USE BLUE INK							
1. LAST NAME (PRINT)							
SMITH							
2. FIRST NAME (PRINT)							
DOUGLAS							
3. MIDDLE NAME (PRINT)							
EDWARD							
4. A. BIRTH DATE (MM/DD/YYYY) B. BIRTH PLACE (CITY, STATE, COUNTRY)							
2/2/20 2/2/22 060562							
5. A. SERVICE BRANCH (PRINT) B. SERVICE NUMBER							
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6. A. LAST NAME (PRINT) B. FIRST NAME (PRINT) C. MIDDLE NAME (PRINT)							
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VA FORM 10-9009a (15)

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NAME: SMITH, DONALD
SSN: 222-00-2222

16. VETERANS EXPOSURE TO ENVIRONMENTAL FACTORS (ENTER APPROPRIATE CODES)		
16A. ARE YOU CURRENTLY SMOKING CIGARETTES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16B. IF NO, GO TO ITEM 16E.	YES/NO	YES Y
16B. IF YES, HOW MANY YEARS HAVE YOU BEEN SMOKING CIGARETTES? ENTER THE NUMBER OF YEARS IN BLOCK 16B AND 16C.	YES/NO	20 Y
16C. ON THE AVERAGE, HOW MANY PAGES ARE YOU SMOKING PER DAY? ENTER THE NUMBER OF PAGES IN BLOCKS 16B AND 16D.	YES/NO	21 Y
16D. HAVE YOU SMOKED CIGARETTES IN THE PAST? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16E. IF NO, GO TO ITEM 16G.	YES/NO	Y
16E. IF YES, HOW MANY YEARS HAD YOU SMOKED? ENTER NUMBER OF YEARS IN BLOCKS 16E AND 16F.	YES/NO	20 Y
16F. ON THE AVERAGE, HOW MANY PAGES DID YOU SMOKE PER DAY? ENTER THE NUMBER OF PAGES IN BLOCKS 16E AND 16F.	YES/NO	21 Y
16G. EXPOSURE TO THE PERSIAN GULF DO YOU BELIEVE YOU WERE EXPOSED TO ANY OF THE FOLLOWING:		
16G.1. SMOKE FROM OIL FIREFIGHT ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	Y
16G.2. SMOKE OR FLAMES FROM TENT HEATERS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	Y
16G.3. CIGARETTE SMOKE (PERSIAN) FROM OTHERS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	Y
16G.4. DIESEL AND/OR OTHER PETROCHEMICAL FLAMES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	Y
16G.5. EXPOSURE TO BURNING TRASH/FIRE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	Y
16G.6. BURN EXPOSURE TO DIESEL OR OTHER PETROCHEMICAL FUELS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	Y
16G.7. OTHER CHEMICAL AGENTS (PERSIAN) COMPANIES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	Y
16G.8. OTHER PESTICIDES AND/OR SOLVENTS AND/OR PETROCHEMICAL SUBSTANCES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	Y
16G.9. DEFLECTED URINARY? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	N
16G.10. MICROBES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	N
16G.11. PERSONAL PESTICIDE USE, INCLUDING CREAMS, SPRAYS OR FLEA COLLARS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	Y
16G.12. NERVE GAS OR OTHER NERVE AGENTS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	N
16G.13. DRUG (PYRIDOSTIGMINE) USED TO PROTECT AGAINST NERVE AGENTS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	Y
16G.14. MUSTARD GAS OR OTHER AGENTS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	N
16G.15. ATE OR DRANK FOOD CONTAMINATED WITH SMOKE, OIL OR OTHER CHEMICAL? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 16G.	YES/NO UNKNOWN	Y

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Change 2
Chapter 2
APPENDIX 2CNAME: SMITH, DOUGLAS
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107. ATE FOOD OTHER THAN PROVIDED BY ARMED FORCES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 208.	YES (B) NO (A)	2
108. BATHED IN OR DRANK WATER CONTAMINATED WITH BACILLI OR OTHER CHEMICAL? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 208.	YES (B) NO (A)	2
109. BATHED IN WATER OTHER THAN PROVIDED BY ARMED FORCES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 208.	YES (B) NO (A)	2
110. IMMUNIZATION AGAINST ANTHRAX? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 210.	YES (B) NO (A)	2
111. IMMUNIZATION AGAINST BOTULISM? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 210.	YES (B) NO (A)	2
112. OTHER EXPOSURES? ENTER HERE AND IN C-10 ONLY.		
113. DID VETERAN HAVE ANY OF THE FOLLOWING EXPERIENCES WHILE IN THE PERMANENT DRAFT? ENTER APPROPRIATE CODES.		
114. DID YOU EVER GO ON COMBAT PATROLS OR HAVE OTHER VERY DANGEROUS DUTY? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 210.	YES (B) NO (A)	2
115. WERE YOU EVER UNDER SHARP FIRE (INCLUDING "BOMB"?) ENTER ONE OF THE FOLLOWING CODES IN BLOCK 210.	YES (B) NO (A)	3
116. WHAT PERCENTAGE OF PEOPLE IN YOUR UNIT WERE KILLED OR WOUNDED OR MISSING (MIA)? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 210.	YES (B) NO (A)	2
117. HOW OFTEN DID YOU SEE SOMEONE HIT BY BOMBING OR OUTCROSSING? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 210.	YES (B) NO (A)	2
118. HOW OFTEN WERE YOU IN DANGER OF BEING KILLED OR KILLED (I.E. FROD, BOMB, CHEMICAL, AMBUSH, REAR AREA, ETC.)? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 210.	YES (B) NO (A)	2
119. DID YOU WITNESS CHEMICAL ATTACK? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 210.	YES (B) NO (A)	U
120. VETERAN'S HEALTH (MEDICAL'S EVALUATION)		
121. WHICH BEST DESCRIBES VETERAN'S HEALTH AFTER PERIOD OF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 210.		
1 = Very Good 2 = Good 3 = Fair 4 = Poor 5 = Very Poor		
122. VETERAN'S FUNCTIONAL IMPAIRMENT		
123. WHICH BEST DESCRIBES VETERAN'S OWN ASSESSMENT OF FUNCTIONAL IMPAIRMENT? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 210.		
1 = No Impairment 2 = Slight Impairment 3 = Moderate Impairment 4 = Severe Impairment		
124. HOW MANY HOURS WERE LOST BY VETERAN DUE TO ILLNESS IN THE PAST 30 DAYS? ENTER NUMBER OF DAYS LOST IN BLOCKS 221-222.		
0 5		
125. EVIDENCE OF BIRTH DEFECTS AND INFANT DEATHS AMONG VETERAN'S CHILDREN AND PROBLEMS WITH FERTILITY AND INFERTILITY.		
126. HOW MANY CHILDREN DOES VETERAN HAVE? ENTER NUMBER IN BLOCKS 223 AND 224. I.E. 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 00.		
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Change 2
Chapter 2
APPENDIX 2C.

March 21, 1996

NAME SMITH DOUGLAS
SSN 222-40-2222

221. HOW MANY OF THESE CHILDREN WERE BORN WITH BIRTH DEFECTS? (BIRTH DEFECTS ARE ANY STRUCTURAL, FUNCTIONAL, OR BIOCHEMICAL ABNORMALITY AT BIRTH WHETHER GENETICALLY DETERMINED OR INCURRED DURING GESTATION THAT IS NOT DUE TO INJURY SUSTAINED DURING BIRTH.) ENTER NUMBER IN BLOCKS 221 AND 222. IF NONE, GO TO ITEM 223.	221	222
221. HOW MANY OF THESE CHILDREN WERE CONCEIVED BEFORE GULF SERVICE? ENTER THE NUMBER OF CHILDREN IN BLOCKS 221 AND 222. IF NONE, LEAVE BLANK AND GO TO ITEM 223.	221	222
221a. STATE MATERNAL AGE AT CONCEPTION OF FIRST CHILD CONCEIVED BEFORE GULF SERVICE. ENTER AGE IN BLOCKS 221 AND 222.	221a	222a
221. HOW MANY OF THESE CHILDREN WERE CONCEIVED DURING AND AFTER GULF SERVICE? ENTER NUMBER IN BLOCKS 221 AND 222. IF NONE, LEAVE BLANK AND GO TO ITEM 223.	221	222
221a. STATE MATERNAL AGE AT CONCEPTION OF FIRST CHILD CONCEIVED DURING AND AFTER GULF SERVICE. ENTER AGE IN BLOCKS 221 AND 222.	221a	222a
222. HAS VETERAN OR SPOUSE HAD INFERTILITY PROBLEMS? (INFERTILITY PROBLEMS OF VETERAN OR SPOUSE INCLUDING PREMENSTRUAL INFERTILITY - RELATIVE INFERTILITY DEFINED AS INABILITY TO CONCEIVE AFTER 12 OR MORE MONTHS OF INTERCOURSE WITHOUT USE OF CONTRACEPTION AND WHEN NEITHER SPOUSE IS SURGICALLY ESTERILIZED) ENTER ONE OF THE FOLLOWING CODES IN BLOCK 222. IF NO, GO TO ITEM 223.	222	223
222a. HAS VETERAN OR SPOUSE HAD INFERTILITY BEFORE GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 222. IF NO, GO TO ITEM 223.	222a	223a
222a. STATE MATERNAL AGE DURING FIRST ATTEMPTS TO CONCEIVE. ENTER AGE IN BLOCKS 222 AND 223.	222a	223a
222a. HAS VETERAN OR SPOUSE HAD INFERTILITY AFTER RETURN FROM GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 222. IF NO, GO TO ITEM 223.	222a	223a
222a. STATE MATERNAL AGE DURING FIRST ATTEMPTS TO CONCEIVE. ENTER AGE IN BLOCKS 222 AND 223.	222a	223a
223. HAS VETERAN OR SPOUSE HAD MISCARriages (NOTE: MISCARriages ARE SPONTANEOUS EXPULSION OF THE PRODUCTS OF CONCEPTION BEFORE 36 WEEKS OF GESTATION - SPONTANEOUS ABORTION) ENTER ONE OF THE FOLLOWING CODES IN BLOCK 241. IF NO, GO TO ITEM 224.	223	241
223a. HAS VETERAN OR SPOUSE HAD MISCARriages BEFORE PERMANENT GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 241. IF NO, GO TO ITEM 224.	223a	241a
223a. STATE MATERNAL AGE AT CONCEPTION. ENTER AGE IN BLOCKS 241 AND 242.	223a	241a
223a. HAS VETERAN OR SPOUSE HAD MISCARriages AFTER PERMANENT GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 241. IF NO, GO TO ITEM 224.	223a	241a
223a. STATE MATERNAL AGE AT CONCEPTION. ENTER AGE IN BLOCKS 241 AND 242.	223a	241a
224. HAS VETERAN OR SPOUSE HAD STILLBIRTHS (NOTE: STILLBIRTH IS BIRTH AFTER 20 WEEKS OF GESTATION OF AN INFANT WHO SHOWED NO EVIDENCE OF LIFE AFTER BIRTH) ENTER ONE OF THE FOLLOWING CODES IN BLOCK 241. IF NO, GO TO ITEM 224.	224	241
224a. HAS VETERAN OR SPOUSE HAD STILLBIRTHS BEFORE GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 241. IF NO, GO TO ITEM 224.	224a	241a
224a. STATE MATERNAL AGE AT CONCEPTION. ENTER AGE IN BLOCKS 241 AND 242.	224a	241a
224a. HAS VETERAN OR SPOUSE HAD STILLBIRTHS AFTER RETURN FROM GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 241. IF NO, GO TO ITEM 224.	224a	241a
224a. STATE MATERNAL AGE AT CONCEPTION. ENTER AGE IN BLOCKS 241 AND 242.	224a	241a
225. HAS VETERAN OR SPOUSE HAD INFANT DEATHS (NOTE: DEATH THAT OCCURRED WITHIN ONE YEAR OF BIRTH (AND/OR BARRIED BORN ALIVE) ENTER ONE OF THE FOLLOWING CODES IN BLOCK 241. IF NO, GO TO ITEM 225.	225	241
225a. HAS VETERAN OR SPOUSE HAD INFANT DEATHS BEFORE GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 241. IF NO, GO TO ITEM 225.	225a	241a
225a. STATE MATERNAL AGE AT CONCEPTION. ENTER AGE IN BLOCKS 241 AND 242.	225a	241a
225a. HAS VETERAN OR SPOUSE HAD INFANT DEATHS AFTER GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 241. IF NO, GO TO ITEM 225.	225a	241a
225a. STATE MATERNAL AGE AT CONCEPTION. ENTER AGE IN BLOCKS 241 AND 242.	225a	241a

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Chapter 2
APPENDIX 2C

NAME: SMITH, DOUGLAS
SSN: 222-00-2222

ESTIMATE MATERNAL AGE AT CONCEPTION, ENTER AGE IN BLOCKS 281 AND 282, ID 283.		(281-282)														
280. IF A WOMAN VETERAN REPORTS SHE WAS PREGNANT IN PERSIAN GULF, RECORD DATE OF CHILD'S BIRTH AND HOSPITAL OF BIRTH HERE AND IN VETERAN'S CHS ONLY TO FACILITATE FOLLOWUP, IF RECORDED. (AAC WILL NOT ENTER THIS DATA IN FOR DISKBASE)																
DATE OF BIRTH		HOSPITAL OF BIRTH														
NAME OF HOSPITAL		LOCATION														
PART II TO BE COMPLETED BY EXAMINING PHYSICIAN																
<table border="1"> <tr> <th colspan="3">31. DATE OF EXAM</th> </tr> <tr> <th>MONTH</th> <th>DAY</th> <th>YEAR</th> </tr> <tr> <td>013</td> <td>013</td> <td>19715</td> </tr> </table>		31. DATE OF EXAM			MONTH	DAY	YEAR	013	013	19715	<table border="1"> <tr> <th>34. TOTAL NO. OF VETERAN'S COMPLAINTS</th> <th>(371-372)</th> </tr> <tr> <td>06</td> <td></td> </tr> </table>		34. TOTAL NO. OF VETERAN'S COMPLAINTS	(371-372)	06	
31. DATE OF EXAM																
MONTH	DAY	YEAR														
013	013	19715														
34. TOTAL NO. OF VETERAN'S COMPLAINTS	(371-372)															
06																
35A. LINKUP TO TEN MAJOR CURRENT SYMPTOMS, ICD 9 CODES, NO. & YR OF ONSET, DURATION IN MOSE AND IF SYMPTOM IS CURRENTLY PRESENT ON LINKS A-J, ITEM 36, IF VETERAN HAS MORE THAN 10, ENTER THE MOST SEVERE ADDITIONAL SYMPTOMS IN CHN, LINK CODES LINK ITEM 8, BLOCKS 271-280 FOR ICD-9-CM CODES.																
(1) DESCRIBE SYMPTOM NARRATIVE	(2) ICD-9-CODES	(3) NO. & YR OF ONSET MONTH YEAR	(4) DURATION (MOSE)	(5) CURRENTLY PRESENT Y/N (YES=1, NO=0)												
A. FATIGUE	(273-277)	1/8/97	(283-284)	1/8/97												
B. DIZZINESS	(278-282)	1/8/97	(283-284)	1/8/97												
C. INSOMNIA	(283-287)	1/8/97	(283-284)	1/8/97												
D. HEADACHES	(288-292)	1/8/97	(283-284)	1/8/97												
E. COUGH	(293-297)	1/8/97	(283-284)	1/8/97												
F. JOINT PAIN	(298-302)	1/8/97	(283-284)	1/8/97												
G.	(303-307)		(283-284)													
H.	(308-312)		(283-284)													
I.	(313-317)		(283-284)													
J.	(318-322)		(283-284)													
36. LIST MOST SEVERE SYMPTOM (A SYMPTOM FROM ITEM A-J, WHICH VETERAN CONSIDERS THE MOST SEVERE I.E. CHIEF COMPLAINT), ENTER ICD-9-CM CODE IN BLOCKS 418-425.																
36. DIAGNOSTIC CONSULTATION, ENTER THE FOLLOWING CODES IN BLOCKS 418-425.																
36.1. NO CONSULTATION DONE 36.2. ALLERGY/IMMUNOLOGY CONSULTATION DONE 36.3. ALLERGY/IMMUNOLOGY CONSULTATION DONE, NO DIAGNOSIS																
36.4. ALLERGY/IMMUNOLOGY CONSULTATION DONE, NO DIAGNOSIS																
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36.97. ALLERGY/IMMUNOLOGY CONSULTATION DONE, NO DIAGNOSIS																
36.98. ALLERGY/IMMUNOLOGY CONSULTATION DONE, NO DIAGNOSIS																
36.99. ALLERGY/IMMUNOLOGY CONSULTATION DONE, NO DIAGNOSIS																
36.100. ALLERGY/IMMUNOLOGY CONSULTATION DONE, NO DIAGNOSIS																

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March 21, 1996

NAME: SMITH, DOUGLAS
SSN: 222-44-2222

I. HEMATOLOGY/ONCOLOGY, BLOCK 428	1	(108)
J. INFECTIOUS DISEASES/PARASITOLOGY, BLOCK 427	1	(107)
K. NEPHROLOGY, BLOCK 428	4	(108)
L. NEUROLOGY, BLOCK 428	1	(108)
M. OCCUPATIONAL MEDICINE, BLOCK 430	3	(108)
N. PULMONARY, BLOCK 431	3	(107)
O. PSYCHIATRY, BLOCK 432	3	(108)
P. PSYCHOLOGY/PSYCHOMETRIC TESTING, BLOCK 433	1	(103)
Q. RHEUMATOLOGY, BLOCK 434	3	(104)
R. OTHER, ENTER FOLLOWING CODES IN BLOCK 435		
Y=YES	☒ (103)	
N=NO		
S. ADDITIONAL WORKUPS/CONSULTATIONS PERFORMED WHICH WERE NOT LISTED IN ITEMS 28A-Q. LIST HERE AND IN CHR.		

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NAME: SMITH, DOUGLAS
SSN: 333-00-3333

27A. DESCRIBE DIAGNOSIS (Numbered)		ICD-9-CM (Number)	
A. (PRIMARY)	<u>OSTEOARTHRITIS, GENERALIZED</u>	710	500
B.	<u>RHINITIS, DUE TO POLLEN</u>	471	90
C.			
D.			
E.			
F.			
G.			
H.			
I.			
J.			

NOTE: CODES DO NOT REPEAT OR LIST SYMPTOM CODE ALREADY LISTED UNDER ITEM 27A.

28. BLOCK 28 DIAGNOSIS IS MADE, ENTER "Y" IN BLOCK 28 RIGHT, OTHERWISE, LEAVE BLANK. THIS ITEM MUST BE COMPLETED IN CONJUNCTION WITH ITEM 27 "DIAGNOSIS"

28. DISPOSITION (Enter with Y for YES or N for NO)			
28A. DISPOSITIONED BY YOUR FIRM PERSONNEL	28B. DISPOSITIONED BY YOUR FIRM PERSONNEL	28C. DISPOSITIONED BY YOUR FIRM PERSONNEL	28D. DISPOSITIONED BY YOUR FIRM PERSONNEL
Y	N	N	N
28E. DISPOSITIONED BY YOUR FIRM PERSONNEL	28F. DISPOSITIONED BY YOUR FIRM PERSONNEL	28G. DISPOSITIONED BY YOUR FIRM PERSONNEL	28H. DISPOSITIONED BY YOUR FIRM PERSONNEL
Y	N	N	N
28I. DISPOSITIONED BY YOUR FIRM PERSONNEL	28J. DISPOSITIONED BY YOUR FIRM PERSONNEL	28K. DISPOSITIONED BY YOUR FIRM PERSONNEL	28L. DISPOSITIONED BY YOUR FIRM PERSONNEL
N	N	N	N

29. ENTER THE DISPOSITION CODE, ENTERING 0000 IF NOT KNOWN, IF 0.

30. NAME OF PHYSICIAN (Print Full Name)

31. NAME OF PHYSICIAN (Print Full Name)

32. NAME OF PHYSICIAN (Print Full Name)

33. NAME OF PHYSICIAN (Print Full Name)

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REPORTING REQUIREMENTS

1. **Submission.** *NOTE: The use of Persian Gulf Code Sheet, VA Form 10-9009A, December 1991, will be discontinued on September 24, 1995. Existing stock must be destroyed. All completed Persian Gulf Code Sheets dated December 1991, and submitted to Austin Automation Center (AAC) on and after September 24, 1995, will be rejected and returned to the submitting VA facility. The use of revised VA Form 10-9009A, dated July 1995, must be implemented on September 25, 1995. Requirements on the submission of Department of Veterans Affairs (VA) Form 10-9009A (July 1995), Persian Gulf Registry Code Sheet are as follows:*

- a. Legible copies of completed code sheets are submitted to the Office of Financial Management Austin Automation Center (AAC), Austin, TX, for data entry into the Persian Gulf Registry (PGR).
- b. Originals are to be maintained in veteran's Consolidated Health Record (CHR).
- c. Code sheets need to be scanned to ensure all required fields are completed.
- d. No medical record documentation should be attached to these code sheets.
- e. Code sheets will not be returned to facility of origin unless corrections are required.
- f. AAC will send copies of code sheets, once entered into the PGR, to the Senior Registry Coordinator, Environmental Agents Service (103A), Department of Veterans Affairs, 810 Vermont Avenue, N.W., Washington, DC 20420, for disposition.

2. **Batching of Code Sheets**a. **Preparation**

(1) VA Form 10-9009A (July 1995) code sheets, Parts I through III, are provided in booklet form. If any of the pages are removed, they should be stapled in the upper-left hand corner.

(2) Completed code sheets must be batched in groups of no more than 25.

(3) Facilities and/or a division of a consolidated facility must keep submissions separate, i.e., each batch will include code sheets from one facility. These code sheets should be arranged in numerical order according to the Social Security Number (SSN), i.e., lowest SSN first and highest SSN last).

NOTE: *Corrected code sheets do not have to be batched separately. They can be mailed with the regular code sheets as long as they are from the same facility.*

b. If a veteran has had two examinations within the same mailing period, that is, an initial and a follow-up examination, only the initial examination code sheet should be submitted in the batch. Hold the follow-up examination code sheet until you are certain the AAC has processed and accepted the initial examination code sheet. If submitted simultaneously, an error message may occur.

3. **Transmittal Form (See App. 2E.)**

a. Three copies of VA Form 7252 (formerly VA Form 30-7252), Transmittal Form for the Use in Shipment of Tabulating Data, must accompany each batch of code sheets. One copy must be retained at the AAC and the other copy will be returned by the AAC to the transmitting facility acknowledging receipt of code sheets and the third will include any rejected code sheets and the edit analysis printout, entitled "Transaction Change and Error (Reject) Listing."

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b. If there were no examinations or code sheets processed for each month, a transmittal form must be completed indicating "0" for the "Code Sheet Count" and sent to the AAC. This will assist the AAC in maintaining a control on the code sheets transmitted by each facility.

(1) As batches are prepared for submission to the AAC an entry should be made on the batch control log.

(2) Using the control log, assign the appropriate number and record it on the transmittal form.

(a) Begin with batch number 001 for January of each year and continue with sequential numbers throughout the year.

(b) Example: If there are 50 code sheets to be submitted to the AAC during the month of January, prepare two batches of 25 per batch, with the control log number 001 and 002.

c. The Persian Gulf control log must consist of the following:

(1) Facility code number,

(2) Batch number assigned sequentially by facility beginning with 001 in January of each year (also to be recorded on transmittal sheet);

(3) Number of code sheets in the batch (also to be recorded on the transmittal sheet),

(4) Date the batch(es) was(were) mailed to the AAC, and

(5) Date the batch(es) and associated edit output was(were) returned from the AAC.

4. Mailing

a. Code sheets must be submitted to the AAC monthly according to the following schedule:

(1) Region 1, the 6th of the month.

(2) Region 2, the 10th of the month.

(3) Region 3, the 14th of the month.

(4) Region 4, the 18th of the month.

b. The mailing address for the AAC is:

Department of Veterans Affairs
 Automation Center (200/397A)
 ATTN: PERSIAN GULF CLERK
 1615 Woodward Street
 Austin, TX 78772-0001

c. It is not appropriate to call the AAC in regard to questions on code sheet completion or correction. These questions should be referred to the Veterans Registry Coordinator(s), the Environmental Agents Service, VA Central Office.

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d. The AAC will process the data from the code sheets twice each month (10th and 25th). The AAC will return all batches with the printout "Transaction Change and Error (Reject) Listing" to the transmitting facility.

5. Transaction Change and Error (Reject) Listing

a. A computerized printout "Transaction Change and Error (Reject) Listing" will be returned to the transmitting facility with the processed code sheets.

(1) This printout will reflect:

- (a) Rejected records, i.e., edit errors identified by an asterisk(*);
- (b) Other messages not necessarily rejecting records; and
- (c) The number of records inputted, i.e., accepted as well as rejected.

(2) Facilities must verify the number of code sheets sent to the AAC against the printout.

b. Corrections are to be made on the returned code sheet with RED pen or RED felt-tipped pen or a new code sheet can be made with the correction in the appropriate field(s). If a new code sheet is prepared for the return of a correction, do not complete just the corrected fields. **NOTE: All of the fields must be completed as if it were an initial input.**

c. Examples of the messages on the listing and the corrective action to be taken are listed as follows:

(1) Message. "This record rejected for edit errors."

Action: Correct error(s) (*) and resubmit code sheet.

(2) Message. "Transaction accepted, initial examination already established at (facility number); transaction will be processed as a follow-up examination for your facility."

Action: AAC will not return a code sheet to the facility since it has been accepted as a follow-up examination. Original code sheet on file at facility should be corrected and card file or computerized record should reflect the facility number where initial examination was performed.

(3) Message. "Transaction accepted but an initial examination is needed. Action Required."

Action: The registry does not contain an initial examination record for this veteran, but the registry has accepted the follow-up examination record that was submitted. Reconstruct, if possible, the initial examination record and submit to the AAC. A code sheet will not be returned to the facility on this transaction since it has been accepted in the PGR as a follow-up examination.

(4) Message. "Duplicate Follow-up Segment."

Action: This message will appear if the examination date on the code sheet submitted on the veteran is identical to an examination date already existing in the registry. There is the possibility of a coding or entry error. Examination date should be verified using the veteran's medical record. If there is a duplicate record, it should be deleted by submitting a code sheet in accordance with instructions for deleting a record.

(5) Message. "No matching initial examination."

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Action: When deletion of an initial record in the registry is attempted, the code sheet submitted with a type "B" must have the identical information as on the original record previously accepted into the registry, otherwise deletion process cannot be carried out.

6. Miscellaneous

a. Forms Acquisition. Forms can be obtained from the VA Forms and Publication Depot through local channels. VA Form 30-7252 has been changed to VA Form 7252. The form itself has not been revised.

(1) Facilities can use either form when submitting reports. An initial supply of VA Form 10-9009A (July 1995), has been provided to each facility.

(2) Additional forms can be obtained from the Depot.

b. Reports Control Symbol. Reports Control Symbol (RCS) 10-0860 applies to this reporting requirement.

(1) The original code sheet will be filed in the veteran's CHR with the documentation, i.e., laboratory test results, etc., from the PGR examination and one legible copy sent to the AAC to be entered in the PGR.

(2) If a CHR does not already exist for a veteran, one will be established. A locator card will be created with the establishment of the CHR. *NOTE: It is highly recommended that all registry records are maintained in a separate section of CHR where they are easily identifiable for quality monitoring and research availability.*

c. Record Disposition. Refer to Records Control Schedule 10-1, Section XXII, Item No. 136-5 for record disposition (see Medical Administration Service).

d. Records Retention. Refer to Records Control Schedule 10-1 for records retention. Persian Gulf examination information will be made part of the perpetual medical record at medical facilities following the same retention requirements specified for VA CHR's Agent Orange and Ionizing Radiation examinations. This includes:

(1) VA Form 10-9009A (July 1995),

(2) Progress notes,

(3) Laboratory reports,

(4) Patient locator cards, and

(5) Any other documentation that may have been part of a PGR examination.

INSTRUCTIONS AND SAMPLE OF COMPLETED VA FORM 7252,
TRANSMITTAL FORM FOR USE IN SHIPMENT OF TABULATING DATA

1. Item 1. Addressee. Department of Veterans Affairs Automation Center (200/397), 1615 Woodward Street, Austin, TX 78722-0001, ATTN: Persian Gulf Clerk.
2. Item 2. Facility name and address. - Enter facility name and address.
3. Item 3. Reply reference. - Enter facility number and routing symbol.
4. Item 4. Leave blank.
5. Item 5. Number of packages. - Enter number of batches.
6. Item 6. Dispatch Date. - Enter date submitting to the Office of Financial Management Austin Automation Center (AAC).
7. Item 6a. Final Batch. - Leave blank.
8. Item 7. Official Responsible for Shipment. - Enter name, title and FTS telephone number of individual responsible for transmitting code sheets to the AAC.
9. Item 8. Tabulating Data.
 - a. Column A. Enter Records Control Symbol number 10-0860.
 - b. Column B. Job Number. Enter "12" in first segment and "22A1" in second segment.
 - c. Column C. Description.
 - (1) First line enter "PERSIAN GULF;"
 - (2) Second line enter "Facility Number;"
 - (3) Third line enter "Batch Number;"
 - (4) Fourth line enter "Code Sheet Count;" and
 - (5) Fifth line enter "Cumulative Count." NOTE: *This figure should be the total number of veterans who have had registry examinations since the onset of the Persian Gulf Registry Program in 1992.*
 - (d) Columns D and E. Leave blank.
10. Item 9. Remarks. Enter number of VA Form 10-9009A's (July 1995).

August 6, 1993

1A

SAMPLE OF COMPLETED VA FORM 7252

TRANSMITTAL FORM FOR USE IN SHIPMENT OF TABULATING DATA					
1. ADDRESSEE Department of Veterans Affairs Austin Automation Center (200-397) 1615 Woodward Street Austin, TX 78772-0001			2. STATION NAME AND ADDRESS VA Medical Center 50 Irving Street, N.W. Washington, DC 20001		
			3. REPLY REFERENCE (Ref. No./symbol) 688/136	4. EFFECTIVE DATE OF DATA	
5. NO. OF PACKAGES 1	6. DISPATCH DATE 8/1/95	6A. FINAL BATCH (Check)	7. OFFICIAL RESPONSIBLE FOR SHIPMENT (Name, title and signature) Joe Doe FTS #700-921-0000 Veterans' Registry Coordinator		
8. TABULATING DATA					
REPORTS CON- TROL SYMBOL (A)	JOB NUMBER (B)	DESCRIPTION (C)		NO. OF COPIES OF REPORTS (D)	CARD COUNT (E)
10-0860	10 20A1	PERSIAN GULF			
		Facility Number - 688			
		Batch Number - 003			
		Code Sheet Count - 25			
		Cumulative Count - 75			
9. REMARKS VA Form 10-9009A's (July 1995)					

VA FORM
MAR 1972 7252EXISTING STOCK OF VA FORM 30-7252,
MAR 1966, WILL BE USED.

* U.S.G.P.O. 1988 - 302-991/7252A

March 21, 1996

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**INSTRUCTIONS AND SAMPLE FORMAT FOR COMPLETION OF BI-MONTHLY REPORT ON
 PERSIAN GULF WAR VETERANS REGISTRY
 EXAMINATIONS (RCS 10-0860)**

A bi-monthly report is required from all Department of Veterans Affairs (VA) facilities providing up-to-date statistical information on Persian Gulf Registry (PGR) examinations. Instructions are provided below for the completion and submission of this report.

1. **Date of Report.** Each report should include the date the report was prepared and submitted to the following address:

2. **Mailing Address.** This report should be transmitted to the following address:

Department of Veterans Affairs
 Environmental Agents Service (131)
 ATTN: Persian Gulf Coordinator
 810 Vermont Avenue, N.W.
 Washington, DC 20420

3. **Mailing Date.** This report should be sent to the above address **NO LATER THAN 5 WORKING DAYS FOLLOWING THE END OF EACH BI-MONTHLY REPORTING PERIOD.**

4. The following statistical information is required (see sample 2F-3 and 2F-4).

a. **Initial Examination.** (The first physical examination of the Persian Gulf veteran.) List the total number of completed initial examinations performed during the current 2-month reporting period. *NOTE: A completed code sheet has already been sent to Austin Automation Center (AAC) which was completed for the purpose of entering a Persian Gulf veteran into the PGR. This count should be verified with the computerized or card file records maintained at each facility (see par. 2.04) describing the computerized or card file requirement.*

b. **Cumulative Initial Examinations.** The total number of cumulative initial examinations listed in the previous bi-monthly report.

c. **Cumulative Initial Examination.** The total number of "first-time" examinations performed by the medical facility since the beginning of the PGR in 1992. This number should include the current month's initial examinations (par. 4a) plus the sum of the previous month's cumulative initial examinations (par. 4b). *NOTE: Examinations performed by satellite outpatient clinics should be included in the total cumulative figure for VA medical center of jurisdiction. Justification for exceptions to this requirement should be directed to EAS (131), VHA Headquarters. Independent outpatient clinics should report in a manner similar to VA medical centers.*

d. **Initial Incomplete Examinations (In process).** The total number of incomplete (code sheet(s) that has/have not been sent to AAC) initial examinations in process during the period of the current report.

e. **Follow-up Examinations.** (A first-time examination subsequent to the initial examination-a completed initial examination code sheet has been sent to AAC.) The total number of follow-up examinations during the period of the current report.

f. **Cumulative Follow-up Examinations.** The total number of follow-up examinations performed by the medical facility since the beginning of the registry in 1992. This total should be the sum of the previous months' cumulative follow-up examination total and the current bi-monthly follow-up examinations.

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g. **Follow-up Examinations in Process.** The total number of follow-up examinations being processed (completed code sheet(s) has/have not been sent to AAC).

h. **Pending Examination Appointments.** The total number of initial Persian Gulf examinations for which appointments have been scheduled beyond the end of the bi-monthly report period. *NOTE: This is not cumulative and applies to the current bi-monthly report.*

i. **Next Appointment Date.** Indicate the next available appointment date.

j. **Number of Veterans Failing to Keep an Initial Examination Appointment.** The total number of veterans who failed to keep a scheduled appointment during the bi-monthly reporting report. *NOTE: This is not cumulative and applies to reporting period only.*

k. **Comments or Problems Regarding Pending Examination Appointments.** Problems or challenges should be documented with comments regarding examination workload. An explanation and action plan to alleviate delays should be provided in situations where a facility has 50 or more examinations pending, and/or the next available appointment is more than 30 days beyond the date of request. If statistics have been adjusted due to AAC acceptance of code sheets, the message "Cumulative statistics adjusted per transaction acceptance at AAC" need to be included in this paragraph.

l. **Name and Telephone Number.** The name and telephone number of the person preparing the report must be indicated.

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SAMPLE FORMAT FOR BI-MONTHLY REPORT ON PERSIAN GULF VETERANS
 (RCS-10-0860)



DEPARTMENT OF VETERANS AFFAIRS
 Medical Center
 Anywhere, USA 85012

August 7, 1995

In Reply Refer To:

Department of Veterans Affairs
 Environmental Agents Service (131)
 ATTN: Persian Gulf Coordinator
 810 Vermont Avenue, N.W.
 Washington, DC 20420

SUBJECT: Bi-monthly Report of Persian Gulf War Veteran Registry Examinations,
 (RCS-10-0860) - Period Ending July 31, 1995 (Station #600)

The subject report is submitted for the 2-month period ending July 31, 1995:

- a. Initial Examination (Current Bi-Monthly Reporting Period):
 List total number of completed initial examinations performed for 2-month
 period ending July 31, 1995 (i.e. total number of Persian Gulf Registry
 code sheets submitted to Austin Automation Center (AAC): 100
 - b. Cumulative Initial Examinations from Previous Bi-Monthly Report: +450
 - c. Cumulative Number of Completed Initial Examinations Performed
 Since Onset of Program (August, 1992):
 Total of numbers listed in Paragraphs 1-a and 1-b. 550
- Note: This should be the total number of all initial examination code sheets
 submitted to AAC since onset of program. If code sheets have not been sent
 to AAC, do not include in this total.*
- d. Initial Incomplete Examinations (In process):
 Total number of initial (incomplete) examinations in process:
 (code sheets have not been sent to AAC): 75
 - e. Follow-Up Examinations (Code Sheets Sent To AAC):
 Total number of follow-up examinations performed for current reporting period
 (follow-up examinations are those performed subsequent to the initial
 examination where a completed code sheet for an initial examination has
 been sent to AAC): 15

March 21, 1996

f. Cumulative Follow-up Examinations:

Includes the total of follow-up examinations performed (this total includes the number listed in above (par. 1-e) and all follow-up examinations previously reported since August, 1992):

75

g. Follow-up Examinations in Process:

Total number of follow-up examinations in process (code sheets have not been sent to AAC during this reporting period):

12

h. Pending Examination Appointments:

Total number of initial examinations for which appointments have been scheduled beyond the end of the bi-monthly report period:

20

i. The next Available Appointment Date:

8/10/95

j. Number of Veterans Failing to Keep an Initial Examination Appointment:

Total number of veterans who failed to keep a scheduled appointment during the current bi-monthly reporting period. This is not cumulative.

10

k. Comments/problems regarding pending examinations: None

l. The name, address and telephone number of the person preparing this report:

(Signature)

John Doe
 Medical Center Director

August 8, 1995

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Chapter 2
APPENDIX 2Q

EXAMPLES OF PERSIAN GULF REGISTRY FOLLOW-UP LETTERS

SAMPLE PERSIAN GULF REGISTRY FOLLOW-UP LETTER
(MEDICAL PROBLEMS INDICATED)DEPARTMENT OF VETERANS AFFAIRS
Medical Center
Anywhere, U.S.A. Zip

In Response Reply To:

(Date)

(Name/Address)

Dear _____:

We sincerely appreciate your recent participation in the Department of Veterans Affairs (VA) Persian Gulf Registry. This effort should prove to be helpful in assisting us to serve you and other veterans who are concerned about the possible health problems which may have resulted from service in Southwest Asia during the Persian Gulf War.

As discussed at the conclusion of your visit, results of your examination and laboratory tests showed certain problems (optional—these findings may be described in lay terms). In view of these findings, we have scheduled you for treatment of these health problems on (date). If for any reason you cannot keep this appointment, please call (telephone number) at the earliest possible time to cancel and reschedule.

The results of your examination will be maintained by VA and will be available for future use as needed. If you have any questions or concerns about your Persian Gulf Registry examination, please contact the Veterans' Registry Coordinator at (telephone number) for assistance.

Whether you are entitled to cost-free treatment or will be responsible for partial co-payment will be determined by your income and other factors unless the VA determines that your health problems are service connected. You may wish to file a claim for compensation to establish possible service connection. The injury or illness need not have been incurred in combat; the law requires only that a disease or disability was incurred or aggravated during military service.

Please remember that this examination does not automatically initiate a claim for VA benefits. If you wish to file a claim, please contact your nearest VA Regional Office. In your area, the Regional Office is located at (address). Their telephone number is (telephone number). If you need any further assistance, you may contact a Veterans' Benefits Counselor by calling the VA toll-free telephone number 1-800-827-1000.

An outreach program has been implemented by which VA notifies all individuals listed in the Registry of significant VA activities, including the health consequences of military service in the Persian Gulf theater of operations during the Persian Gulf War. You will be receiving a "Persian Gulf Review" which is published periodically by VA's Environmental Agents Service. A copy of this "Review" is enclosed for your reference.

We trust this information is helpful to you. Once again, your participation in the registry is appreciated.

Sincerely,

(Signature)

Name of Veterans' Registry Physician

Enclosure

August 8, 1995

SAMPLE PERSIAN GULF REGISTRY FOLLOW-UP LETTER
(NO MEDICAL PROBLEMS INDICATED)



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
Anywhere, U.S.A. Zip

In Response Reply To:

(Date)

Name/Address

Dear _____:

We sincerely appreciate your recent participation in the Department of Veterans Affairs (VA) Persian Gulf Registry. This effort should prove to be helpful in assisting us to serve you and other veterans who are concerned about the possible health problems which may have resulted from service in Southwest Asia during the Persian Gulf War.

As discussed at the conclusion of your visit, results of your examination and laboratory tests indicate that there are no detectable medical problems. At this time you have no reason to be concerned about any adverse health effects resulting from your service in the Persian Gulf. However, in the future if you have a medical problem, I would encourage you to seek the help and advice of your nearest VA medical center or outpatient clinic. You may reach us at (telephone number).

The results of your examination will be maintained by VA and will be available for future use as needed.

Please remember that this examination does not automatically initiate a claim for VA benefits. If you wish to file a claim, please contact your nearest VA Regional Office. In your area, the Regional Office is located at (address). Their telephone number is (telephone number). If you need any further assistance, you may contact a Veterans' Benefits Counselor by calling the VA toll-free telephone number 1-800-827-1000.

An outreach program has been implemented by which VA notifies all individuals listed in the Registry of significant VA activities, including the health consequences of military service in the Persian Gulf theater of operations during the Persian Gulf War. You will be receiving a "Persian Gulf Review" which is published periodically by VA's Environmental Agents Service. A copy of this "Review" is enclosed for your reference.

We trust this information is helpful to you. Once again, your participation in the registry is appreciated.

Sincerely,

(Signature)

Name of Veterans' Registry Physician

Enclosure

August 8, 1995

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Chapter 3

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Chapter 3

CHAPTER 3. PHASE II, PERSIAN GULF UNIFORM CASE ASSESSMENT PROTOCOL (UCAP)

3.01 PURPOSE

This chapter provides a Uniform Case Assessment Protocol (UCAP) for the evaluation of Persian Gulf veterans with unexplained illnesses.

3.02 BACKGROUND

a. Many of the almost 690,000 personnel who served in the Persian Gulf have reported health problems since their return to the United States. While most of the health problems of these veterans have been diagnosed as conditions that are readily definable, some veterans have unexplained illnesses which developed after their Persian Gulf service. Many of the Gulf War veterans seen by Department of Veterans Affairs (VA) Veterans Registry Physicians (VRPs) have complex, multifaceted health problems that provide difficult diagnostic challenges. Veterans are understandably frustrated that definitive answers regarding the cause(s) of their problems are not immediately forthcoming.

b. VA and the Department of Defense (DOD) working cooperatively developed a UCAP for the evaluation of these Persian Gulf veterans who after a thorough routine medical evaluation are determined to have unexplained illnesses. NOTE: *This UCAP, grew out of the medical experience in diagnostic evaluation of Gulf War veterans seen at VA Referral Centers. The protocol was then further refined and adapted for use by both VA and DOD facilities.*

c. The UCAP includes a group of supplemental baseline laboratory tests and consultations which should be provided to every veteran with debilitating unexplained illness. It gives guidelines for the minimum diagnostic work-up of the most frequent complaints experienced by Gulf War veterans with unexplained illnesses. This protocol utilizes validated and readily available diagnostic tests to thoroughly evaluate each of the common symptoms reported by Gulf War veterans.

d. The concept behind the protocol was to identify previously unrecognized major diagnostic entities which could provide an explanation for the symptoms commonly reported in Persian Gulf veterans with unexplained illnesses. It should be emphasized that the protocol is not designed to be all-encompassing; therefore, it needs to be carried out with a high degree of clinical judgment. All significant symptoms and abnormalities not specifically outlined in the protocol, must be fully evaluated according to the medical judgment of the VRP who is directing the work-up. The information gathered by this process is to be entered into a computerized database through the use of VA Form 10-9009A (July 1995), Persian Gulf Registry Code Sheet, Part III (see App. 3B), and will be analyzed for patterns of disease.

3.03 AUTHORITY

The UCAP for Persian Gulf veterans with unexplained illnesses was administratively established by the Under Secretary for Health to assist in addressing the unique health concerns of the Persian Gulf veterans. On November 2, 1994, Public Law (Pub. L.) 103-446 amended Title 38 United States Code (U.S.C.) 1117 implementing the uniform and comprehensive medical evaluation protocol for the veterans of the Persian Gulf War.

3.04 POLICY

It is VA policy that all VA health care facilities must examine the available services for Persian Gulf veterans to ensure that quality outreach, diagnostic, and treatment services are furnished as intended; and if these services cannot be provided by the local VA facility, a mechanism must be developed to provide these services by contract, sharing agreements or referral to other VA facilities.

3.05 RESPONSIBILITIES

a. **VRPs.** The responsibility of the VRP is to:

- (1) Conduct the Registry examination (Phase I), which is the first step toward diagnosis of the health problems of a Persian Gulf veteran; and
- (2) If a diagnosis is not readily apparent after conducting routine medical evaluations, to initiate the UCAP, (Phase II) using the protocol provided in Appendix 3A.

b. **Veterans' Registry Coordinators (VRCs)** The VRC is responsible for:

- (1) Reporting Instructions as included in Appendix 2D and Appendix 3B.
- (2) Providing accurate coding of both symptoms and diagnoses and ,when questions arise about these items, consult with VRP, or designee.
- (3) Completing and submitting the UCAP and VA Form 10-9009A (July 1995) through appropriate channels to VA Central Office of Environmental Agents Service (EAS). *NOTE: Related questions may be referred to EAS, telephone (202) 565-4183.*

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UNIFORM CASE ASSESSMENT PROTOCOL (UCAP)

1. Phase I Level Laboratory Evaluations

- a. Complete Blood Count (CBC),
- b. Urinalysis, and
- c. Blood Chemistry - SMA-6.

2. Phase II-Level Evaluation Protocol. Phase II Level Evaluations are recommended for those veterans after complete clinically indicated evaluations are conducted and the physician determines that the patient has an unexplained illness. Individuals who after completing Phase I or Registry evaluations, have a disability and do not have a clearly defined diagnosis which explains their symptoms, must receive the following supplemental baseline laboratory tests and consultations.

a. Supplemental Baseline Laboratory Tests

- (1) CBC,
- (2) Sedimentation Rate Erythrocyte Sedimentation Rate (ESR),
- (3) C-Reactive Protein,
- (4) Rheumatoid Factor,
- (5) Anti-Nuclear Antibody (ANA),
- (6) Liver Function,
- (7) Creatine Phosphokinase (CPK),
- (8) Hepatitis Serology,
- (9) Human Immuno-deficiency (HIV),
- (10) Venereal Disease Research Laboratory (VDRL),
- (11) B-12 and Folate,
- (12) Thyroid function Test,
- (13) Urinalysis, and
- (14) Tuberculosis (TB) skin test Purified Protein Derivative (PPD).

b. Consultations, to include:

- (1) Dental, but only if participant's annual screening is not done.
- (2) Infectious Disease.
- (3) Psychiatry, but only with physician-administered instruments.

(a) Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised (DSM III-R). **NOTE: Delete nodules for mania and psychosis.**

(b) Clinician Administered Post Traumatic Stress Disorder (PTSD) Scale (CAPS).

(4) Neuropsychological Testing, but only as indicated by a psychiatry consult.

c. **Symptom-specific Examination.** Individuals who have the following symptoms should have the listed minimum work-up.

(1) **Diarrhea**, to include:

(a) Gastrointestinal (GI) consult,

(b) Stool for Ova and Parasites (O&P),

(c) Stool Leukocytes,

(d) Stool Culture,

(e) Stool Volume,

(f) Colonoscopy with biopsies, and

(g) Esophagoduodenoscopy (EGD) with biopsies and aspiration.

(2) **Abdominal pain** to include:

(a) GI consult,

(b) EGD with biopsy and aspiration,

(c) Colonoscopy with biopsy,

(d) Abdominal Ultrasound,

(e) Upper Gastrointestinal (UGI) series with small bowel follow-through, and

(f) Abdominal Computed Tomography (CT) Scan.

(3) **Headache**

(a) Magnetic Resonance Imaging (MRI) of the head, and

(b) Lumbar Puncture (LP) to include:

1. Glucose,

2. Protein,

3. Cell Count,

4. VDRL,

5. Oligoclonal (IgG),

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- 6. Myelin basic protein.
- 7. Opening pressure, and
- 8. Neurology.
 - (4) Muscle Aches and/or Numbness
 - (a) Electromyogram (EMG), and
 - (b) Nerve Conduction Velocity (NCV).
 - (5) **Memory Loss**, only if verified by neuropsychological testing, to include:
 - (a) Magnetic Resonance Imaging (MRI),
 - (b) LP, **NOTE:** *See tests on headache evaluation.*
 - (c) Neurology consult,
 - (d) Neuro-psychological testing.
 - (6) **Vertigo and/or Tinnitus**, to include:
 - (a) Audiogram,
 - (b) Electronystamogram (ENG), and
 - (c) Brainstem Auditory Evoked Response (BAER).
 - (7) **Chronic Fatigue**, to include:
 - (a) Polysomnography, and
 - (b) Multiple Sleep Latency Test (MSLT).
 - (8) **Chronic Cough and/or Shortness of Breath**, to include:
 - (a) Pulmonary Consult,
 - (b) Pulmonary Function Test (PFT) with exercise and Arterial Blood Gases (ABG),
 - (c) If routine PFT's are negative, perform Methacholine challenge test, and
 - (d) Bronchoscopy with biopsy and/or lavage which is to be considered if PFTs are normal.
 - (9) **Chest Pain and/or Palpitations**, to include:
 - (a) Electrocardiogram (ECG),
 - (b) Exercise Stress Test, and
 - (c) Holter monitor.

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- (10) Skin Rash, to include:
 - (a) Dermatology consult, and
 - (b) Consider a biopsy.
 - (11) Reproductive Concerns, to include for:
 - (a) Males, an urology consult; and
 - (b) Females, a gynecology (GYN) consult.
- (c) Additional elements recommended for the evaluation of Persian Gulf veterans with complaints of Reproductive Health Problems (RHP):
1. Detailed genitourinary history and/or problems, e.g.:
 - a. Sexual,
 - b. Genitourinary symptoms,
 - c. Menstrual,
 - d. Contraceptive practices,
 - e. Pregnancy-related,
 - f. Conception,
 - g. Birth defects,
 - h. Congenital disorders,
 - i. Menopause,
 - j. Prior infections,
 - k. Prior surgery, and
 - l. Exposures to toxic agents, etc.
 2. Detailed genital/pelvic examination.
 3. Laboratory and ancillary testing, e.g.:
 - a. Pap tests; and
 - b. Tests for genitourinary infections.
 4. Urologist consultation for male veterans who have RHP that cannot be diagnosed or managed successfully by primary care practitioners.
 5. Gynecology consultation for female veterans who have RHP that cannot be diagnosed or managed successfully by primary care practitioners.

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(d) Additional elements for evaluation of Persian Gulf veterans with complaints of infertility.

1. Detailed menstrual and reproductive history (such as the Infertility Questionnaire utilized by Walter Reed Army Medical Center*).

2. Semen analysis, e.g.:

a. Volume.

b. pH.

c. Liquefaction.

d. Sperm concentration.

e. Motility.

f. Progressive motility.

g. Sperm viability.

h. Leukocytes, and

i. Morphology.

3. Referral to an infertility specialist or program.

(e). Additional elements for evaluation of Persian Gulf veterans with complaints related to birth defects or genetic disorders in offspring conceived during or after Persian Gulf service.

1. Detailed history of congenital or genetic disorders (such as the Patient Genetic Screen Questionnaire utilized by Walter Reed Army Medical Center*).

2. Detailed occupational exposures questionnaire (such as Worker and Supervisor Questionnaires utilized by National Naval Medical Center*).

3. Referral to a genetic disease specialist or program.

* For copies of these questionnaires (Items d-1 and e-1 and 2) contact VA Environmental Agents Service (103A) at 202-565-4183.

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 APPENDIX 3B

INSTRUCTIONS AND SAMPLE FORMAT FOR COMPLETION OF
 VA FORM 10-9009A (JULY 1995), PERSIAN GULF REGISTRY CODE SHEET, PART III,
 UNIFORM CASE ASSESSMENT PROTOCOL (UCAP), PHASE II

1. General Instructions for Completing Department of Veterans Affairs (VA) Form 10-9009A, Part III, Phase II Persian Gulf Registry Examination.

a. The Phase II examination (VA Form 10-9009A, Part III) should be offered to all eligible Persian Gulf War veterans with unexplained illnesses. The Phase II examination should be performed after the completion of the Phase I registry examination and a thorough clinically-based evaluation of the veteran's symptoms as deemed necessary by the examining physician.

b. Phase II should be performed at the local VA medical facility or if the medical expertise is unavailable, local referral must be made to the nearest regional tertiary care center or Persian Gulf Referral Center.

c. Reporting requirements described in Appendix 2D will apply to, VA Form 10-9009A, Part III.

(1) Part III of the code sheet must be completed at the time of the examination by the veteran's registry physician (VRP). A completed Part III will be returned to Medical Administration Service (MAS) for completion of ICD-9-CM codes where appropriate.

(2) A bi-monthly report of Phase II examinations is to be sent to Department of Veterans Affairs, Environmental Agents Service (131), 810 Vermont Avenue, N.W., Washington, DC 20420, 5 work days following the end of each reporting period (refer to instructions and sample report in App. 3B).

2. Instructions for Completing VA Form 10-9009A, Part III, Phase II

a. Tests and Consultations **NOTE:** *Only those items which are related to the veteran's symptoms and deemed necessary by the examining physicians should be completed; leave test and consult questions that are not applicable blank.*

(1) Item 1. Blocks 1-24. Were the following tests performed? Enter one of the following codes in designated blocks:

Y = Yes
 N = No

(2) Item 2. Blocks 1-18. Blood Tests

- (a) Block 1. Complete Blood Count (CBC)?
- (b) Block 2. Skin Erythema Dose (SED) Rate?
- (c) Block 3. C-Reactive Protein?
- (d) Block 4. Rheumatoid Factor?
- (e) Block 5. Fluorescent Anti-Nuclear Antibody (ANA)?
- (f) Block 6. SGOT (AST) (Glutamic Oxaloacetic Transaminase)?
- (g) Block 7. SGPT (ALT) (Transaminase Glutamic Pyruvate)?
- (h) Block 8. Lactic Acid Hydrogenase (LDH)?

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- (i) Block 9. Alkaline Phosphatase
- (j) Block 10. Creatine Phosphokinase (CPK)?
- (k) Block 11. Hepatitis B Surface Antibody?
- (l) Block 12. Hepatitis B Core Antigen?
- (m) Block 13. Venereal Disease Research Laboratory (VDRL)?
- (n) Block 14. Vitamin B-12?
- (o) Block 15. Folate?
- (p) Block 16. Human Immuno-deficiency (HIV)?
- (q) Block 17. Thyroxine Total Serum (T4)?
- (r) Block 18. Thyroid Stimulating Hormone (TSH)?
- (3) **Item 3. Block 19. Urinalysis?**
- (4) **Item 4. Block 20. Tuberculosis (TB) Skin Test Purified Protein Derivative (PPD)?**
- (5) **Item 5. Block 21. Chest X-ray?**
- (6) **Item 6. Block 22. Psychiatric Consultation?**
 - (a) Item 6A. Block 23. Structured Clinical Interview for Diagnoses (SCID) for Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised (DSM-III-R). Was the SCID interview given?
 - (b) Item 6B. Block 24. Clinical Administered Post-Traumatic Stress Disorder (PTSD) Scale (CAPS). Was the CAPS performed?
- (7) **Item 7. Blocks 25-39. List of Diagnoses.** Designated physician staff or physician assistants are to provide narrative description of diagnoses. If none, leave blank. **NOTE: MAS coders: Enter ICD-9-CM codes in Blocks 25-39.**
- (8) **Item 8. Block 40. Psychology-Neuropsychological Test.** Was this test performed? Enter one of the following codes in Block 40.
 - Y = Yes
 - N = No
- (9) **Item 8A. Blocks 41-55. List of Diagnoses.** Designated physician staff or physician assistants are to provide narrative description of diagnoses. If none, leave blank. **NOTE: MAS coders: Enter ICD-9-CM codes in Blocks 41-55.**
- (10) **Item 9. Block 56. Infectious Disease-Screening Examination.** Was this examination performed? Enter one of the following codes in Block 56.
 - Y = Yes
 - N = No.

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(11) Item 9A. Blocks 57-66. List of Diagnoses. Designated physician staff or physician assistants are to provide narrative description of diagnoses. If none, leave blank. **NOTE: MAS coders: Enter ICD-9-CM codes in Blocks 57-66.**

(12) Item 10. Block 67. Dental Examination. If there was a medical indication, was this examination performed? Enter one of the following codes in Block 67.

Y = Yes
N = No

(13) Item 10A. Blocks 68-77. List of Diagnoses. Designated dental staff are to provide narrative description of diagnoses. If none, leave blank. **NOTE: MAS coders: Enter ICD-9-CM codes in Blocks 68-77.**

SYMPTOM-SPECIFIC EXAMINATIONS , PHASE II **NOTE: Complete only those questions which are appropriate to the veteran's symptoms; otherwise leave these blocks blank.**

(14) Item 11. Blocks 78-98. Diarrhea and/or Abdominal Pain

(a) Item 11A. Block 78. Did patient receive a GI (Gastroenterology) consult? Enter one of the following codes in Block 78.

Y = Yes
N = No

(b) Item 11B. Blocks 79-98. List Diagnoses. Designated physician staff are to provide narrative description of diagnoses. If none, leave blank. **NOTE: MAS coders: Enter ICD-9-CM codes in Blocks 79-98.**

(15) Item 12. Blocks 99-109. Headache and/or Memory Loss

(a) Block 12A. Block 99. Did patient receive neurology consult? Enter one of the following codes in Block 99:

Y = Yes
N = No

(b) Item 12B. Blocks 100-109. List Diagnoses. Designated physician staff are to provide narrative description of diagnoses. If none, leave blank. **NOTE: MAS coders: Enter ICD-9-CM codes in Blocks 100-109.**

(16) Item 13. Blocks 110-120. Muscle Aches or Numbness

(a) Item 13A. Block 110. Did patient receive a neurology consult? Enter one of the following codes in Block 110.

Y = Yes
N = No

(b) Item 13B. Blocks 111-120. List Diagnoses. Designated physician staff are to provide narrative description of diagnoses. If none, leave blank. **NOTE: MAS coders: Enter ICD-9-CM codes in Blocks 111-120.**

(17) Item 14. Blocks 121-131. Chronic Fatigue

(a) Item 14A. Block 121. Did patient receive consult(s) relating to chronic fatigue? Enter one of the following codes in Block 121.

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(b) Item 14B, Blocks 122-131. List Diagnoses. Designated physician staff are to provide narrative description of diagnoses. If none, leave blank. **NOTE: MAS coders: Enter ICD-9-CM codes in Blocks 122-131.**

(18) Item 15. Blocks 132-142. Joint Pain

(a) Item 15A, Block 132. Rheumatology Consult. Did patient receive rheumatology consult? Enter one of the following codes in Block 132:

Y = Yes
 N = No

(b) Item 15B, Blocks 133-142. List Diagnoses. Designated physician staff are to provide narrative description of diagnoses. If none, leave blank. **NOTE: MAS coders: Enter ICD-9-CM codes in Blocks 133-142.**

(19) Item 16. Blocks 143-153. Chronic Cough and/or Shortness of Breath

(a) Item 16A, Block 143. Pulmonary Consult. Did patient receive pulmonary consult? Enter one of the following codes in Block 143:

Y = Yes
 N = No

(b) Item 16B, Blocks 144-153. List Diagnoses. Designated physician staff are to provide narrative description of diagnoses. If none, leave blank. **NOTE: MAS coders: Enter ICD-9-CM codes in Blocks 144-153.**

(20) Item 17. Blocks 154-164. Skin Rash

(a) Item 17A, Block 154. Dermatology Consult. Did patient receive a dermatology consult? Enter one of the following codes in Block 154.

Y = Yes
 N = No

(b) Item 17B, Blocks 155-164. List Diagnoses. Designated physician staff are to provide narrative description of diagnoses. If none, leave blank. **NOTE: MAS coders: Enter ICD-9-CM codes in Blocks 155-164.**

(21) Item 18. Blocks 165-175. Vertigo and/or Tinnitus

(a) Item 18A, Block 165. Audiology consult? Did patient receive an audiology consult? Enter one of the following codes in Block 165:

Y = Yes
 N = No

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(b) Item 18B, Blocks 166-175. List Diagnoses. Designated physician staff are to provide narrative description of diagnoses. If none, leave blank. NOTE: *MAS coders: Enter ICD-9-CM codes in Blocks 166-175.*

(22) Item 19, Blocks 176-185. Chest Pain and/or Palpitations

(a) Item 19A, Block 176. Cardiology Consult? Did patient receive a cardiology consult? Enter one of the following codes in Block 176:

Y = Yes
N = No

(b) Item 19B, Blocks 177-186. List Diagnoses. Designated physician staff are to provide narrative description of diagnoses. If none, leave blank. NOTE: *MAS coders: Enter ICD-9-CM codes in Blocks 177-186.*

(23) Item 20, Blocks 187-198. Reproductive Concerns

(a) Item 20A, Block 187. Did male patient receive a urology consult? Enter of the following codes in Block 187.

Y = Yes
N = No

(b) Item 20B, Block 188. Did female patient receive a gynecology consult? Enter one of the following codes in Block 188.

Y = Yes
N = No

(c) Item 20C, Blocks 189-198. List Diagnoses. Designated physician staff are to provide narrative description of diagnoses. If none, leave blank. NOTE: *MAS coders: Enter ICD-9-CM codes in Blocks 189-198.*

(24) Item 21, Blocks 199-248. Final Diagnoses. List up to 10 major definite medical diagnoses on lines 21A-J, with the primary diagnosis listed on line 21A. If no diagnosis is made, leave these lines blank as well as blocks for ICD-9 codes. NOTE: *MAS coders: Use ICD-9-CM codes in first five numbered blocks of each diagnosis.*

(25) Item 22, Block 249. After completing UCAP, Phase II, the physician feels that the veteran has an unexplained illness? Enter one of the following codes in Block 249.

Y = Yes
N = No.

APPENDIX 3B

SSN: 222-00-2222

PART III PHASE II - UNIFORM CASE ASSESSMENT (UCA)			
1. WERE THE FOLLOWING TESTS PERFORMED? Enter the following codes in blocks 1-24. Y = YES N = NO			
2. BLOOD TESTS. BLOCKS 1-18; OTHER - BLOCKS 19-24.			
A. CBC (COMPLETE BLOOD COUNT)	(1)	B. SED RATE (SIN ERYTHRA DOSE)	(2)
D. RHEMATOID FACTOR?	(4)	E. FLUORESCENT ANA1 (ANTINUCLEAR ANTI-BODY)	(5)
G. SGPT (ALT) (TRANSAMINASE GLUTAMIC PYRUVATE)	(7)	H. LDH (LACTIC ACID HYDROGENASE)	(8)
J. CKT CREATINE PHOSPHOGENASE	(10)	K. HEPATITIS B SURFACE ANTIBODY?	(11)
M. VDRL (VENERICAL DISEASE RESEARCH LABORATORY)	(13)	N. VITAMIN B-12	(14)
P. HIV (HUMAN IMMUNO DEFICIENCY)	(16)	Q. T4 (THYROIDINE TOTAL SERUM)?	(17)
S. URINALYSIS	(19)	T. TB SKIN TEST (PPD) (TUBERCULOSIS SKIN TEST PURIFIED PROTEIN DERIVATIVE)	(20)
V. PSYCHIATRIC EVALUATION?	(22)	W. SCID FOR DSM-IV-R (STRUCTURED CLINICAL INTERVIEW FOR DIAGNOSIS)	(23)
		X. CAPS PTSD SCALE (CLINICAL ADMINISTERED POST TRAUMATIC STRESS DISORDER)	(24)
7. LIST DIAGNOSES: MAS CODERS: ENTER ICD-9-CM CODE IN BLOCKS 25-39. IF NONE, LEAVE BLANK.			
DESCRIBE DIAGNOSES (Maximum)			
1.		(25)	(26) (27) (28) (29)
2.		(30)	(31) (32) (33) (34)
3.		(35)	(36) (37) (38) (39)
8. PSYCHOLOGIST/NEUROPSYCHOLOGICAL TEST? (Enter code in block 40)	(40)	8A. LIST DIAGNOSES: MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 41-46. IF NONE, LEAVE BLANK.	
Y=Yes N=No		DESCRIBE DIAGNOSES (Maximum)	
		(41)	(42) (43) (44) (45)
		(46)	(47) (48) (49) (50)
		(51)	(52) (53) (54) (55)
9. INFECTIOUS DISEASE - SCREENING EXAM? (Enter code in block 56)	(56)	9A. LIST DIAGNOSES: MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 57-66. IF NONE, LEAVE BLANK.	
Y=Yes N=No		DESCRIBE DIAGNOSES (Maximum)	
		(57)	(58) (59) (60) (61)
		(62)	(63) (64) (65) (66)
10. DENTAL EXAM? (Enter code in block 67)	(67)	10A. LIST DIAGNOSES: MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 68-77. IF NONE, LEAVE BLANK.	
Y=Yes N=No		DESCRIBE DIAGNOSES (Maximum)	
		(68)	(69) (70) (71) (72)
		(73)	(74) (75) (76) (77)

D

SAMPLE OF COMPLETED VA FORM 10-9009A, PART III
UCAP (UNIFORM CASE ASSESSMENT PROTOCOL) PHASE III

3B-6

Chapter 3
APPENDIX 3B

August 8, 1995

NAME: SMITH, DOUGLAS
SSN: 222-00-2222

19. CHEST PAIN AND/OR PALPITATIONS							
18A. CARDIOLOGY CONSULT (Enter code in block 176) Y-YES N-NO	176	18B. LIST DIAGNOSES. MAS CODERS ENTER ICD-9-CM CODES IN BLOCKS 199-199 IF NONE, LEAVE BLANK. DESCRIBE DIAGNOSES (Maximum)					
		ICD-9-CM CODES					
		1.	(177)	(178)	(179)	(180)	(181)
		2.	(182)	(183)	(184)	(185)	(186)
20. REPRODUCTIVE CONCERNS							
20A. MALES - UROLOGY CONSULT? (Enter code in block 187) Y-YES N-NO	187	18B. LIST DIAGNOSES. MAS CODERS ENTER ICD-9-CM CODES IN BLOCKS 199-199 IF NONE, LEAVE BLANK. DESCRIBE DIAGNOSES (Maximum)					
		ICD-9-CM CODES					
		1.	(189)	(190)	(191)	(192)	(193)
		2.	(194)	(195)	(196)	(197)	(198)
20B. FEMALES - GYN CONSULT? (Enter code in block 188) Y-YES N-NO	188	18B. LIST DIAGNOSES. MAS CODERS ENTER ICD-9-CM CODES IN BLOCKS 199-199 IF NONE, LEAVE BLANK. DESCRIBE DIAGNOSES (Maximum)					
		ICD-9-CM CODES					
		1.	(199)	(200)	(201)	(202)	(203)
		2.	(204)	(205)	(206)	(207)	(208)
		3.	(209)	(210)	(211)	(212)	(213)
		4.	(214)	(215)	(216)	(217)	(218)
		5.	(219)	(220)	(221)	(222)	(223)
		6.	(224)	(225)	(226)	(227)	(228)
		7.	(229)	(230)	(231)	(232)	(233)
		8.	(234)	(235)	(236)	(237)	(238)
		9.	(239)	(240)	(241)	(242)	(243)
		10.	(244)	(245)	(246)	(247)	(248)
		11.	(249)	(250)	(251)	(252)	(253)
		12.	(254)	(255)	(256)	(257)	(258)
		13.	(259)	(260)	(261)	(262)	(263)
		14.	(264)	(265)	(266)	(267)	(268)
		15.	(269)	(270)	(271)	(272)	(273)
		16.	(274)	(275)	(276)	(277)	(278)
		17.	(279)	(280)	(281)	(282)	(283)
		18.	(284)	(285)	(286)	(287)	(288)
		19.	(289)	(290)	(291)	(292)	(293)
		20.	(294)	(295)	(296)	(297)	(298)
		21.	(299)	(300)	(301)	(302)	(303)
		22.	(304)	(305)	(306)	(307)	(308)
		23.	(309)	(310)	(311)	(312)	(313)
		24.	(314)	(315)	(316)	(317)	(318)
		25.	(319)	(320)	(321)	(322)	(323)
		26.	(324)	(325)	(326)	(327)	(328)
		27.	(329)	(330)	(331)	(332)	(333)
		28.	(334)	(335)	(336)	(337)	(338)
		29.	(339)	(340)	(341)	(342)	(343)
		30.	(344)	(345)	(346)	(347)	(348)
		31.	(349)	(350)	(351)	(352)	(353)
		32.	(354)	(355)	(356)	(357)	(358)
		33.	(359)	(360)	(361)	(362)	(363)
		34.	(364)	(365)	(366)	(367)	(368)
		35.	(369)	(370)	(371)	(372)	(373)
		36.	(374)	(375)	(376)	(377)	(378)
		37.	(379)	(380)	(381)	(382)	(383)
		38.	(384)	(385)	(386)	(387)	(388)
		39.	(389)	(390)	(391)	(392)	(393)
		40.	(394)	(395)	(396)	(397)	(398)
		41.	(399)	(400)	(401)	(402)	(403)
		42.	(404)	(405)	(406)	(407)	(408)
		43.	(409)	(410)	(411)	(412)	(413)
		44.	(414)	(415)	(416)	(417)	(418)
		45.	(419)	(420)	(421)	(422)	(423)
		46.	(424)	(425)	(426)	(427)	(428)
		47.	(429)	(430)	(431)	(432)	(433)
		48.	(434)	(435)	(436)	(437)	(438)
		49.	(439)	(440)	(441)	(442)	(443)
		50.	(444)	(445)	(446)	(447)	(448)
		51.	(449)	(450)	(451)	(452)	(453)
		52.	(454)	(455)	(456)	(457)	(458)
		53.	(459)	(460)	(461)	(462)	(463)
		54.	(464)	(465)	(466)	(467)	(468)
		55.	(469)	(470)	(471)	(472)	(473)
		56.	(474)	(475)	(476)	(477)	(478)
		57.	(479)	(480)	(481)	(482)	(483)
		58.	(484)	(485)	(486)	(487)	(488)
		59.	(489)	(490)	(491)	(492)	(493)
		60.	(494)	(495)	(496)	(497)	(498)
		61.	(499)	(500)	(501)	(502)	(503)
		62.	(504)	(505)	(506)	(507)	(508)
		63.	(509)	(510)	(511)	(512)	(513)
		64.	(514)	(515)	(516)	(517)	(518)
		65.	(519)	(520)	(521)	(522)	(523)
		66.	(524)	(525)	(526)	(527)	(528)
		67.	(529)	(530)	(531)	(532)	(533)
		68.	(534)	(535)	(536)	(537)	(538)
		69.	(539)	(540)	(541)	(542)	(543)
		70.	(544)	(545)	(546)	(547)	(548)
		71.	(549)	(550)	(551)	(552)	(553)
		72.	(554)	(555)	(556)	(557)	(558)
		73.	(559)	(560)	(561)	(562)	(563)
		74.	(564)	(565)	(566)	(567)	(568)
		75.	(569)	(570)	(571)	(572)	(573)
		76.	(574)	(575)	(576)	(577)	(578)
		77.	(579)	(580)	(581)	(582)	(583)
		78.	(584)	(585)	(586)	(587)	(588)
		79.	(589)	(590)	(591)	(592)	(593)
		80.	(594)	(595)	(596)	(597)	(598)
		81.	(599)	(600)	(601)	(602)	(603)
		82.	(604)	(605)	(606)	(607)	(608)
		83.	(609)	(610)	(611)	(612)	(613)
		84.	(614)	(615)	(616)	(617)	(618)
		85.	(619)	(620)	(621)	(622)	(623)
		86.	(624)	(625)	(626)	(627)	(628)
		87.	(629)	(630)	(631)	(632)	(633)
		88.	(634)	(635)	(636)	(637)	(638)
		89.	(639)	(640)	(641)	(642)	(643)
		90.	(644)	(645)	(646)	(647)	(648)
		91.	(649)	(650)	(651)	(652)	(653)
		92.	(654)	(655)	(656)	(657)	(658)
		93.	(659)	(660)	(661)	(662)	(663)
		94.	(664)	(665)	(666)	(667)	(668)
		95.	(669)	(670)	(671)	(672)	(673)
		96.	(674)	(675)	(676)	(677)	(678)
		97.	(679)	(680)	(681)	(682)	(683)
		98.	(684)	(685)	(686)	(687)	(688)
		99.	(689)	(690)	(691)	(692)	(693)
		100.	(694)	(695)	(696)	(697)	(698)
		101.	(699)	(700)	(701)	(702)	(703)
		102.	(704)	(705)	(706)	(707)	(708)
		103.	(709)	(710)	(711)	(712)	(713)
		104.	(714)	(715)	(716)	(717)	(718)
		105.	(719)	(720)	(721)	(722)	(723)
		106.	(724)	(725)	(726)	(727)	(728)
		107.	(729)	(730)	(731)	(732)	(733)
		108.	(734)	(735)	(736)	(737)	(738)
		109.	(739)	(740)	(741)	(742)	(743)
		110.	(744)	(745)	(746)	(747)	(748)
		111.	(749)	(750)	(751)	(752)	(753)
		112.	(754)	(755)	(756)	(757)	(758)
		113.	(759)	(760)	(761)	(762)	(763)
		114.	(764)	(765)	(766)	(767)	(768)
		115.	(769)	(770)	(771)	(772)	(773)
		116.	(774)	(775)	(776)	(777)	(778)
		117.	(779)	(780)	(781)	(782)	(783)
		118.	(784)	(785)	(786)	(787)	(788)
		119.	(789)	(790)	(791)	(792)	(793)
		120.	(794)	(795)	(796)	(797)	(798)
		121.	(799)	(800)	(801)	(802)	(803)
		122.	(804)	(805)	(806)	(807)	(808)
		123.	(809)	(810)	(811)	(812)	(813)
		124.	(814)	(815)	(816)	(817)	(818)
		125.	(819)	(820)	(821)	(822)	(823)
		126.	(824)	(825)	(826)	(827)	(828)
		127.	(829)	(830)	(831)	(832)	(833)
		128.	(834)	(835)	(836)	(837)	(838)
		129.	(839)	(840)	(841)	(842)	(843)
		130.	(844)	(845)	(846)	(847)	(848)
		131.	(849)	(850)	(851)	(852)	(853)
		132.	(854)	(855)	(856)	(857)	(858)
		133.	(859)	(860)	(861)	(862)	(863)
		134.	(864)	(865)	(866)	(867)	(868)
		135.	(869)	(870)	(871)	(872)	(873)
		136.	(874)	(875)	(876)	(877)	(878)
		137.	(879)	(880)	(881)	(882)	(883)
		138.	(884)	(885)	(886)	(887)	(888)
		139.	(889)	(890)	(891)	(892)	(893)
		140.	(894)	(895)	(896)	(897)	(898)
		141.	(899)	(900)	(901)	(902)	(903)
		142.	(904)	(905)	(906)	(907)	(908)
		143.	(909)	(910)	(911)	(912)	(913)
		144.	(914)	(915)	(916)	(917)	(918)
		145.	(919)	(920)	(921)	(922)	(923)
		146.	(924)	(925)	(926)	(927)	(928)
		147.	(929)	(930)	(931)	(932)	(933)
		148.	(934)	(935)	(936)	(937)	(938)
		149.	(939)	(940)	(941)	(942)	(943)
		150.	(944)	(945)	(946)	(947)	(948)
		151.	(949)	(950)	(951)	(952)	(953)
		152.	(954)	(955)	(956)	(957)	(958)
		153.	(959)	(960)	(961)	(962)	(963)
		154.	(964)	(965)	(966)	(967)	(968)
		155.	(969)	(970)	(971)	(972)	(973)
		156.	(974)	(975)	(976)	(977)	(978)
		157.	(979)	(980)	(981)	(982)	(983)
		158.	(984)	(985)	(986)	(987)	(988)
		159.	(989)	(990)	(991)	(992)	(993)
		160.	(994)	(995)	(996)	(997)	(998)
		161.	(999)	(1000)	(1001)	(1002)	(1003)
		162.	(1004)	(1005)	(1006)	(1007)	(1008)
		163.	(1009)	(1010)	(1011)	(1012)	(1013)
		164.	(1014)	(1015)	(1016)	(1017)	(1018)
		165.	(1019)	(1020)	(1021)	(1022)	(1023)
		166.	(1024)	(1025)	(1026)	(1027)	(1028)
		167.					

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**INSTRUCTIONS AND SAMPLE FORMAT FOR COMPLETION OF BI-MONTHLY REPORT
ON PERSIAN GULF UNIFORM CASE ASSESSMENT PROTOCOL (UCAP), PHASE II
(RCS-10-0860)**

A bi-monthly report is required from all Department of Veterans Affairs (VA) facilities for all Persian Gulf veterans receiving a Uniform Case Assessment Protocol (UCAP). Instructions are provided below for the completion and submission of this report: *NOTE: A sample report is provided in Appendix 3C.*

1. **Title of Report:** Bi-monthly Persian Gulf Registry Phase II Examination Report
2. **Reporting Months:** The 2-month reporting period including month and year.
3. **Reporting Facility, Address, and Station Code:** Identify name, address and station code of each reporting facility. If Uniform Case Assessments (UCAs) are performed by satellite outpatient clinics, these clinics should be identified and UCEs reported by VA medical center of jurisdiction.
4. **Column A:** Include the Persian Gulf veteran's name, Social Security Number, (SSN), race, sex and branch of service.
5. **Column B:** If Persian Gulf veteran was an outpatient, indicate this by providing the date of the initial Persian Gulf Registry examination, in Column B.
6. **Column C:** If Persian Gulf veteran was an inpatient, indicate this by providing the date of admission, date of discharge, and the date of the initial Persian Gulf Registry examination in Column C.
7. **Column D:** List up to ten exposures as indicated by veteran.
8. **Column E:** List up to ten symptoms/complaints (with ICD-9 codes) as indicated by veteran.
9. **Column F:** List up to ten diagnoses (with ICD-9 codes). If there are no diagnoses, indicate "None."
10. **Column G:** List all pending tests, consultations, and procedures, if incomplete prior to discharge.
11. **Evaluation:** Summarize the total number of Persian Gulf veterans (inpatients, outpatients receiving UCA's during the current reporting months, and cumulative statistics since the onset of this program (June, 1994). The total number of pending UCA's (those Persian Gulf veterans for whom a UCAE has been scheduled but not performed) should be listed for the current month and not cumulative.
12. **Reporting Information:** Provide the date of this report and the name of the staff member preparing this report and the staff member's telephone contact.
13. **Mailing Address:** This report should be transmitted to the following address:

Department of Veterans Affairs
Environmental Agents Service (103A)
ATTN: Persian Gulf Coordinator
810 Vermont Avenue, N.W.
Washington, DC 20420

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**SAMPLE FORMAT OF BI-MONTHLY PERSIAN GULF REGISTRY PHASE II
UCAP (UNIFORM CASE ASSESSMENT PROTOCOL) REPORT (RCS-10-0860)**

SAMPLE FORMAT OF
BI-MONTHLY PERSIAN GULF REGISTRY PHASE II UCAP (UNIFORM CASE ASSESSMENT PROTOCOL)
REPORT (RCS-10-0860)
REPORTING PERIOD-JUNE-JULY, 1994
VAMC: PHOENIX, AZ (844)

(A)	(B)	(C)	(D)	(E)	(F)	(G)
NAME/SSH/ AGE/RACE/SEX BRANCH OF SERVICE	OUTPATIENT DATE OF EXAMINATION	INPATIENT ADMISSION/ DISCHARGE/ PRGR EXAM DATES	LIST OF EXPOSURES (UP TO TEN)	LIST OF SYMPTOMS (UP TO TEN) & ICD-9 CODES	LIST OF DIAGNOSIS (UP TO TEN) & ICD-9 CODES	PENDING TESTS/CON- SULTATIONS/ PROCEDURES
PRIOR, RICHARD 222-222-2222 30 Y.O.W.M. ARMY	6/17/94		DIESEL FUEL MICROWAVES NERVE GAS ANTHRAX	FATIGUE/ MALAISE (7807)	NEURA- STHENIA (3005)	MRI; THYROID FUNCTION TEST
MAITLAND, JANE 777-777-7777 25 Y.O.B.F. ARMY		7/17/94 7/20/94 8/18/94	SANDFLY OIL WELL SMOKE	JOINT PAIN(78999); RASH (7821); WEIGHT LOSS (7832); HEADACHES (7840); INSOMNIA (78050); DEPRESSION (7800)	MULTIPLE SYMPTOMS OF UNKNOWN ETIOLOGY (7999)	NEURO- PSYCHOLOGICAL

SUMMARIES

	INPATIENT ADMISSIONS	INPATIENT DISCHARGES	OUTPATIENTS	PENDING UCES
CURRENT MONTH:	1	1	1	2
CUMULATIVE:	0	0	0	0
TOTALS:	1	1	1	2

DATE: 8/7/94; PREPARED BY: JANE DOE; PHONE 8002-222-2222

* Y.O.W.M. = Year old white male; ** Y.O.B.F. = Year old black female

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CHAPTER 4. PERSIAN GULF REFERRAL CENTERS (PGRCs)

4.01 PURPOSE

This chapter sets forth clinical and administrative policies concerned with program management of Veterans Health Administration (VHA) Persian Gulf Referral Center (PGRC) examination programs established at Department of Veterans Affairs (VA) Medical Centers in Birmingham, AL, Houston, TX, Washington, DC, and West Los Angeles, CA.

4.02 BACKGROUND

a. In August 1992, VA established three PGRCs to medically assist Persian Gulf veterans whose symptoms defy explanation through the usual diagnostic and therapeutic endeavors of local VA medical centers. An additional center was established in June, 1995. The centers were established when it became clear that increasing number of Desert Storm veterans appeared to be incapacitated and had symptoms which eluded routine medical diagnosis despite thorough medical work-ups at VA medical centers. VA determined that for these veterans it was desirable to provide for inpatient stays to allow for observation, multidisciplinary consultation, documentation of lengthy occupational and exposure histories, and an opportunity for frequent re-examination. For such veterans, local VA medical centers make special arrangements for the transfer, following consultation with the referral center clinicians, to the appropriate center.

b. The referral centers, located at VA Medical Center in Birmingham, AL, Houston, TX, Washington, DC, and West Los Angeles, CA, were selected based on availability of clinical and academic expertise in such areas as pulmonary and infectious diseases, neurology, immunology, neuropsychology and access to toxicologic expertise. The centers place an emphasis on specific symptom complexes, such as fevers of unknown origin, chronic fatigue, memory loss, unexplained weight loss and other adverse health conditions possibly associated with chemical/toxic environmental exposures in the Persian Gulf.

4.03 AUTHORITY

Authority for the VHA PGRCs is provided by Persian Gulf-related legislation including:

a. Public Law (Pub. L.) 102-25 which established a Persian Gulf War period of service affecting persons serving on active duty as of August 2, 1990. At this time, there is no ending date established by law.

b. Pub. L. 102-585, Title VII, "Persian Gulf War Veterans' Health Status Act," enacted November 4, 1992, mandates the Secretary of Veterans Affairs to establish and maintain a Persian Gulf Registry and provide health examinations and counseling for eligible veterans.

c. Pub. L. 103-210, enacted December 20, 1993, provides the Secretary of Veterans Affairs, with authority to provide priority health care for eligible Persian Gulf veterans presenting adverse health conditions possibly associated with service in the Persian Gulf.

4.04 POLICY

Persian Gulf veterans already determined to be eligible for a Persian Gulf Registry examination and/or health care under the authorities cited in paragraphs 2.02 and 3.02, and who have been admitted for outpatient and/or inpatient care at a VA medical center, may be considered for referral to a PGRC. *NOTE: Final eligibility determinations for admission to a PGRC is left to the discretion of the PGRC Director.*

4.05 PROGRAM GUIDANCE

a. Special directives and other program guidance prepared by VA Central Office's Environmental Agents Service (EAS) (103A), provides the basis for PGRC program activities.

b. Appropriate means, i.e., medical center memoranda, need to be taken to circulate this information throughout each Referral Center.

c. PGRC staff must be aware of educational information and other materials and publications prepared by EAS (e.g., Persian Gulf posters, Persian Gulf Reviews, Persian Gulf Staff Updates, Persian Gulf Fact Sheets, etc.).

d. It is expected that PGRC staff will participate in national education meetings and attend periodic nationwide conference calls conducted by the EAS. NOTE: *They should be joined by VA medical center staff concerned with the delivery of health care to Persian Gulf veterans and the maintenance of the Persian Gulf Registry Examination Program.*

4.06 RESPONSIBILITIES

a. PGRC program management requires close coordination and interaction between PGRC staff and VA medical center staff making medical referrals of Persian Gulf veterans with difficult to diagnose health conditions.

b. VA Central Office's EAS (103A) provides program guidance and administratively oversee activities of the PGRCs and referring medical centers.

c. **PGRC Responsibilities.** A specially dedicated clinical and administrative support staff headed by a "Referral Center Clinical Director" is established at each PGRC. The Director is responsible for the clinical management of all medical and administrative activities associated with the special diagnostic program. Major responsibilities include:

(1) Consulting with VA medical center staff to determine appropriateness of referral of Persian Gulf veteran to the PGRC.

(2) Providing medical consultation to VA medical centers of origin for those cases in which it is determined that a PGRC admission is not required. Such consultative support is to assist the local medical center in arriving at a diagnosis and treatment regimen for Persian Gulf veteran(s) in question.

(3) Providing for all administrative aspects of admission, with the close support and assistance of the medical center's Medical Administration Service (MAS), of patient referrals to the PGRC.

(4) Developing a medical plan of action on each referral, i.e.:

(a) Reviewing and confirming the complete medical history in veteran's Consolidated Health Record (CHR),

(b) Providing a comprehensive physical examination,

(c) Providing routine baseline laboratory tests,

(d) Providing other diagnostic testing as required, and

(e) Arranging specialty consultations as determined medically appropriate.

(5) Advising the veteran(s) if they have not already done so, of the opportunity to participate in, and be included in VA's computerized Persian Gulf Veterans Health Registry Examination Program. If veteran wishes to participate in the registry, the PGRC is to ensure compliance with all registry procedures as outlined in M-10, Part III, Chapter 2. NOTE: *Before referral to one of VA's PGRCs, it is requested that all VA medical centers perform a Persian Gulf Registry Examination (Phase I) and if at all possible a Uniform Case Assessment Protocol (UCAP) (Phase II).*

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(6) Providing for the documentation in the veteran's CHR of all medical information pertinent to each referral (PGR code sheets, laboratory reports, etc.).

(7) Upon conclusion of the PGRC's diagnostic work-up of each veteran, providing for administrative referral of that individual back to the referring medical center. The PGRC contacts the medical center of referral prior to the veteran's departure from the facility.

(8) Providing each veteran with a final "consultation" by the PGRC Director, and/or other PGRC staff as designated, of results of diagnostic procedures/treatment.

(9) Providing each referral with a follow-up letter discussing the results of the diagnostic work-up at the PGRC including results of examination and laboratory tests with recommendations, as appropriate, personalized to each referral.

(10) Providing copies of pending test or consultation results for each referred veteran to EAS (103A) and VA facility of origin.

(11) Completing a VA Form 10-9009A (July 1995), Persian Gulf Registry Code Sheet, and sending to Austin Automation Center (AAC) as a follow-up examination when there is a new diagnosis or a change in diagnosis since the initial registry examination code sheet should have been completed by the referral facility and sent to AAC as an initial examination.

(12) Maintaining a special file on each referral at PGRC, for easy accessibility.

(13) Providing cumulative monthly reports to EAS (103A) no later than 5 working days following the end of each month, see paragraph 3.05 and Appendix 3B.

(14) Providing copies of discharge summaries, laboratory test results and code sheets (both initial examination and follow-up, if there is a new diagnosis or a change in diagnosis, for each referred Persian Gulf veteran, to EAS (103A) within 5 working days following the end of each monthly reporting period (see par. 3.05 and App. 3B).

d. Originating Medical Center Responsibilities. VA medical centers are responsible for the medical referral to the PGRCs of those Persian Gulf veterans for whom a medical diagnosis cannot reasonably be determined in spite of extensive diagnostic, including comprehensive clinical examination work-ups. Routine responsibilities of the medical centers making the referral are:

(1) Contacting the Director, PGRC; or other appropriate PGRC clinical staff member to discuss patients who meet the necessary criteria for referral. Referral criteria include:

(a) Performing a Persian Gulf Registry examination, Phase I and Phase II (if facility has these medical capabilities), prior to referral consideration; and

(b) Reviewing medical records of those Persian Gulf veterans with multiple symptoms for which a diagnosis has not been determined or those veterans requiring a "second opinion."

(2) Providing, when necessary, the appropriate PGRC with any documentation which will assist the PGRC in making its determination whether a referral is appropriate, i.e., any examination data described in the patient's CHR including, among others, medical history, progress notes, test results, Persian Gulf Registry diagnostic code sheets, and any other relevant medical/demographic information.

(3) Coordinating with the PGRC clinical and medical administrative service staff, all necessary travel and per diem arrangements for the veteran(s), including dates of planned transfer to the referral center and projected return date.

(4) Obtaining the veteran's permission for transfer and providing counseling concerning the reason(s) for referral, projected period of inpatient admission at the PGRC, travel arrangements and responding to any questions the veteran might have concerning the referral. **NOTE: In some instances veterans may not wish to be referred. Ensure that documentation of the veteran's decision in this regard is fully documented in the CHR progress notes.**

(5) Upon notification of a referral's return from the PGRC, initiating follow-up contact by telephone and/or letter with the veteran within 2 weeks of discharge from the referral center to determine the veteran's health status and to provide any assistance for which the veteran may be eligible.

(6) Discussing with Referral Center Directors outstanding consultation results, either performed at referral centers or to be completed at the local medical centers, and maintained in patient's files at both facilities (local and referral).

(7) Documenting within the veteran's CHR all results, findings and recommendations of the special diagnostic work-up provided by the PGRC.

4.07 REPORTING REQUIREMENTS

a. Originating VA medical centers

- (1) Prepare an original VA Form 10-9009A (July 1995) for each referred Persian Gulf Registry veteran.
- (2) Submit a legible copy to the ACC in accordance with the general instructions found in Appendix 2C.
- (3) Submit a legible copy of the VA Form 10-9009A (July 1995) to the PGRC with the patient's CHR.
- (4) Submit all follow-up results of specialty consultations obtained after the veteran's discharge from a PGRC, including further consultation with the veteran, if appropriate, to:

Department of Veterans Affairs
EAS (103)
ATTN: Senior Registry Coordinator
810 Vermont Avenue, N.W.
Washington, DC 20420

b. PGRC

- (1) Submit follow-up Persian Gulf Code Sheets (VA Form 10-9009A (July 1995)) to AAC when new diagnostic code differs from previously submitted code sheets, (see App.2B).
- (2) Submit a PGRC report of admissions and/or discharges to EAS (103A) . Attn.: Senior Registry Coordinator, within 5 working days following the end of each reporting month (refer to App. 2B for instructions and sample format).
- (3) Submit a negative PGRC report if there were no admissions or discharges during the reporting month.
- (4) Submit copies of discharge summaries, laboratory reports, i.e., chest x-ray, blood count, blood chemistries or enzyme studies, urinalysis and code sheets to EAS (103A), Attn.: Senior Registry Coordinator, no later than 10 working days following the end of each month.
- (5) Submit all original medical records to local VA medical center to be maintained in veteran's CHR.
- (6) Maintain copies at PGRC in a special file for each referred patient.

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(7) Submit copies of results of follow-up specialty consultation after discharge of veteran from PGRC to EAS and local VA medical center for patient's CHR and/or further consultation with veteran, if appropriate.

4.08 MEDIA AND OTHER EXTERNAL CONTACTS

a. **Media Contacts.** Reports of Contact from various media sources (e.g., radio, television, newspapers, etc.) concerning PGRC activities will be referred by phone to the facility public affairs officer. Interviews should not be given unless approved by the medical center Public Affairs Officer who may appropriately coordinate response with the regional VA public affairs representative.

b. **Contacts to Advise Centers of "Special Cures" for Persian Gulf-related Illnesses.** Referral centers can expect, on occasion, to be contacted by private sector physicians, researchers, and the general public with information regarding "quick cures" for Persian Gulf-related illnesses. Such individuals need to be politely advised that:

- (1) There are medically accepted mechanisms to introduce new clinical treatments.
- (2) All new treatments suggested must be reviewed by a formally designated and staffed human subjects review committee.
- (3) It is important to have independent confirmation of treatment efficacy.
- (4) Provisions exist to permit the originator of new therapies to retain professional credit and be appropriately compensated.
- (5) The individual might want to consider presenting the "new approach" at a VA or medical school grand rounds or staff review committee meetings.
- (6) VA and the National Institutes of Health fund quality research proposals.

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APPENDIX 4AINSTRUCTIONS AND SAMPLE FORMAT FOR COMPLETION OF
PERSIAN GULF REFERRAL CENTER MONTHLY REPORT
(RCS-10-0860)

A monthly report is required from all Department of Veterans Affairs (VA) Persian Gulf Referral Centers (PGRC) receiving an extensive, additional diagnostic and therapeutic work-up to evaluate those Persian Gulf War veterans who are incapacitated and experiencing symptoms that have eluded medical diagnosis despite thorough examinations at local VA facilities. The following instructions are provided for the completion and submission of this reported NOTE: *A sample report is provide on page 4A-2.*

1. **Title of Report.** Monthly Persian Gulf Referral Center Report
2. **Reporting Period.** Month and Year of the reporting period.
3. **Reporting Facility, Address and Station Code.** Identify name, address and station code of each reporting PGRC.
4. **Column A.** Include the Persian Gulf veteran's name, Social Security Number, Race, Sex and Branch of Service.
5. **Column B.** Provide the name, city and state of the VA facility from which the Persian Gulf veteran was referred.
6. **Column C.** Indicate date of admission, date of discharge, and the date of Initial Persian Gulf Registry examination.
7. **Column D.** List up to ten exposures as indicated by the veteran.
8. **Column E.** List up to ten symptoms/complaints (with ICD-9 codes) as indicated by the veteran.
9. **Column F.** List up to ten diagnoses (with ICD-9 codes). If there are no diagnoses, -indicate "None."
10. **Column G.** List all pending tests/consultations/procedures, either those that have been performed at the PGRC or those to be performed at the local VA medical center.
11. **Number of Veterans.** List the total number of Persian Gulf veterans admitted, discharged and any pending referrals for current reporting month and cumulative numbers from the onset of this program:
 - a. Total Admissions;
 - b. Total Discharges; and
 - c. Total Referrals Pending: (current month).
12. **Date of Report.** Submit the date of this report.
13. **Contact.** Name of staff member preparing this report and the telephone contact.
14. **Mailing Address.** This report must be transmitted to the following address:

Department of Veterans Affairs
Environmental Agents Service (103A)
ATTN: Persian Gulf Coordinator
810 Vermont Avenue, N.W.
Washington, DC 20420

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PERSIAN GULF REFERRAL CENTER MONTHLY REPORT (RCS 10-0880)
REPORTING MONTH JULY, 1994
PGR: HOUSTON, TX (580)

(A)	(B)	(C)	(D)	(E)	(F)	(G)
NAME/SSN/ AGE/RACE/SEX/ BRANCH OF SERVICE	REFERRED BY: VAMC/OPC	ADMISSION/ DISCHARGE FOR EXAM DATES	LIST OF EXPOSURES (UP TO TEN)	LIST OF SYMPTOMS (UP TO TEN) & ICD-9 CODES	LIST OF DIAGNOSIS (UP TO TEN) & ICD-9 CODES	PENDING TESTS/CON- SULTATIONS/ PROCEDURES
JONES, HARRY 555-55-5555 40 Y.O.W.M. ARMY	ALBANY, NY VAMC	5/1/94 5/10/94 4/11/93	DU; CARC; PESTICIDES	FATIGUE/ MALAISE (7807)	NEURAL- STHENIA (3005)	MRI; THYROID FUNCTION TEST
SMITH, JOHN 333-33-3333 25 Y.O.B.M.* NAVY	MONTROSE, NY VAMC	5/2/94 5/18/94; 3/10/94.	OIL FIRE SMOKE; ANTHRAX VACCINE.	JOINT PAIN (78999); MEMORY LOSS (7809); LOOSE BOWEL STOOLS (7879); FATIGUE (7807); HEARING LOSS (78999); HEADACHES (7840);	MULTIPLE SYMPTOMS OF UNKNOWN ETIOLOGY (7999)	NEURO- PSYCHO- LOGICAL
WRIGHT, ANN 666-66-6666 30 Y.O.W.F.** ARMY	DURHAM VAMC	5/20/94; 5/30/94; 3/4/94.	TENT HEATER SMOKE; ATE LOCAL FOOD; MICROWAVES.	FATIGUE (7807); JOINT PAINS (78999); HEADACHES (7840); SLEEPLESSNESS (78050); LOOSE BOWEL STOOLS (7879)	ARTHRALGIA (7194); DIARRHEA (5684)	NONE

SUMMARIES

CURRENT MO.
CUMULATIVE:

ADMISSIONS
3
10

DISCHARGES:
3
10

PENDING EXAMS:
10
N/A

DATE: 8/7/94;

PREPARED BY: JOHN DOE; PHONE #713-222-222

*Y.O.B.M. (Year Old Black Male)

**Y.O.W.F. (Year Old White Female)

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CHAPTER 5. PERSIAN GULF REGISTRY III FOR SPOUSES AND CHILDREN OF PERSIAN GULF WAR VETERANS

5.01 PURPOSE

This chapter sets forth administrative policies for collection of medical and demographic data on the spouses and children of Persian Gulf War veterans (hereafter referred to as Persian Gulf (PGW) veterans) in an additional and separate registry identified as Persian Gulf Registry III (PGR III) to supplement the Persian Gulf Registry initiated in 1992 and revised in 1995 for PGW veterans.

5.02 AUTHORITY

To respond to concerns about health problems of spouses and children of PGW veterans, the Department of Veterans Affairs (VA) will include in PGR III medical data provided by non-VA, licensed physicians (Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.)). Although the VA has no general/blanket authority to provide registry examinations or treatment to spouses or children of PGW veterans, the Secretary of the Department of Veterans Affairs, hereafter referred to as the Secretary, has been mandated by Public Law (Pub. L.) 103-446, dated November 2, 1994, to include any relevant medical data of spouses and children of PGW veterans in the VA PGR III. These examinations can be provided by non-VA licensed physicians who certify that examinations were conducted using standard protocols and guidelines, provided by VA. These registry data will facilitate program and policy development for PGW veterans.

5.03 ELIGIBILITY

VA includes in PGR III relevant medical data as provided by non-VA physicians of any individual who:

- a. Is a spouse or child of a veteran who is: (1) Listed in the PGW Veteran Registry, established under Pub. L. 102-585, Section 702; and (2) Suffering from an illness or disorder.
- b. Is apparently suffering from, or may have suffered from, an illness or disorder (including a birth defect, miscarriage, or stillbirth) which cannot be disassociated from the veterans service in the Southwest Asia theater of operations.
- c. In the case of a spouse, has granted the Secretary permission to include in the Registry relevant medical data (including a medical history and the results of diagnostic testing and medical examinations) and such other information as the Secretary considers relevant and appropriate with respect to such individual.

5.04 RESPONSIBILITIES

The VA Veterans' Registry Physician (VRP), or designee, Veterans' Registry Coordinator (VRC) and Medical Administration Service (MAS) staff play a significant role in carrying out the mandates of Pub. L. 103-446, in conducting outreach activities to PGW veterans, the veteran's spouses and children, and non-VA physicians (M.D. or D.O.) conducting tests and examinations. In order to ensure uniform collection of medical data, standard protocols, guidelines and code sheets have been developed (refer to App. 5C), with a sample letter of enclosure (refer to App. 5E) and should be provided to any PGW veteran, spouse, child (parent), and non-VA physician requesting copies of these protocols and guidelines.

- a. VRP Responsibilities. The VRP, or designee, is responsible for the clinical management of the program and serves as their primary health care consultant to non-VA physicians, veterans and their families. The VRP will:

- (1) Ensure that the non-VA physician receives guidelines and protocols to be used when performing examinations for spouses and children of PGW veterans.

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(2) Ensure that the non-VA physician receives a cover letter (refer to sample in App. E), with protocols and code sheets to provide a brief background describing the purpose of collecting and recording these medical data.

(3) Review the medical records of every PGW veteran spouse and/or children examined to ensure that a complete physical examination was performed and documented.

(4) Review Part II (Phase I) and III (Phase II) of VA Form 10-9009c, Persian Gulf Registry Code Sheet for Spouses and/or Children, before submission to the Austin Automation Center (AAC) for entry into PGR III.

b. VRC Responsibilities. The VRC is responsible for the administrative management of the program. The VRC will:

(1) Coordinate outreach activities to ensure that all PGW veterans with spouses and/or children with health problems that may be related to veteran's service are aware of VA's commitment to include the veteran's family members in the PGR III.

(2) Enter the results of diagnostic tests, medical histories and medical examinations conducted by licensed non-VA physicians into VA PGR III if requested by the PGW veteran (who must be a registry participant prior to entry of data on spouse or child), spouse, or child.

(3) Provide the appropriate examination guidelines, protocols, code sheets, with cover letters, and other related documentation (refer to App. 5B) for completion by non-VA physician.

(4) Collect data for reporting purposes.

(5) Review the code sheet to further ensure the form's completeness, and, if necessary, obtain and record any missing information from the non-VA physician. *NOTE: Code sheets should be transmitted to AAC no later than 25 working days after receipt from veteran, spouse or non-VA physician.*

(6) Submit completed code sheets to AAC for database entry.

(7) File results of the spouse's or child's diagnostic tests, medical histories, medical examinations, copies of code sheets and other relevant records in PGW veteran's Consolidated Health Record (CHR). *NOTE: These Persian Gulf registry records are subject to the same retention and disposition policies as other medical record files; use Records Control Schedule 10-1.*

c. Code Sheet Completion

(1) The non-VA physician (M.D. or D.O.), will complete Part I of VA Form 10-9009c, and will ensure that all information entered on the code sheet is complete.

(2) The non-VA licensed physician will complete Part II and III of VA Form 10-9009c; refer to instructions and sample code sheet in Appendix 5A.

5.05 REPORTING REQUIREMENTS

The VA's VRCs must submit the following report when received from veteran, spouse, or non-VA physician performing evaluation of veteran's spouse and/or children:

a. VA Form 10-9009c (original) must be prepared monthly and submitted to AAC as per instructions contained in Chapter 2, Appendix 2B. Reports Control Symbol 10-0860 reflects the reporting requirement for VA Form 10-9009c.

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b. VA Form 7252 (formerly VA Form 30-7252), Transmittal Form for the Use in Shipment of Tabulating Data, must be prepared monthly and submitted to AAC, ensuring that code sheets are identified as VA Form 10-9009c for Persian Gulf Spouses or Children, as per instructions contained in Chapter 2, Appendices 2D and 2E.

NOTE: These code sheets should be submitted, based on the following schedule, but no later than 25 working days following receipt from veteran, spouse, child (parent) or non-VA physician.

c. The schedule of mailing dates is as follows for:

- (1) Former Region 1, the 6th of month;
- (2) Former Region 2, the 10th of month;
- (3) Former Region 3, the 14th of month; and
- (4) Former Region 4, the 18th of month.

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PROTOCOL FOR CONDUCTING THE PHYSICAL EXAMINATION, PHASE I, AND ORDERING DIAGNOSTIC STUDIES

1. It is essential that a complete medical history, physical examination and interview be performed by the private physician (Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.)) and documented on appropriate forms. The Department of Veterans Affairs (VA) forms that must be fully completed are: Standard Form 88, Report of Medical Examination, VA Form 10-9009c, Persian Gulf Registry Code Sheet, and Standard Form 509, Progress Notes (for follow-up). These are to be submitted to local VA facility for maintenance in veteran's Consolidated Health Record (CHR). These forms must be provided to the non-VA licensed physician for use when performing examinations of spouses and/or children of Persian Gulf veterans. The complete medical history should address the following: **NOTE: Non-VA physicians may use their own medical examination reports and progress notes as long as they contain the following information:**

- (a) Family history;
- (b) Occupational history;
- (c) Social history including tobacco, alcohol, drug use;
- (d) Civilian exposure(s) history to possible toxic agents;
- (e) Psychosocial history; and
- (f) Review of systems.

2. The person actually performing the physical examination must be identified by name, address, medical license, signature and title (i.e., M.D., D.O., Physician's Assistant, etc.). A licensed physician's countersignature is required if the examiner is a physician's assistant or nurse practitioner.

3. The physician must be aware of the variety of exposures endemic to the Persian Gulf area. These are listed in Appendix 2C and on VA Form 10-9009c. There has been a wide distribution of major categories of diagnoses reported by VA Veterans' Registry Physicians (VRP) and no significant variation in occurrence of major categories of medical problems has been identified. For informational purposes, some of the health problems and/or diseases which should be considered, are as follows:

Unfortunately the International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM) coding system does not give sufficient codes to correctly identify all symptoms and diagnoses. A number of diagnoses that have been reported by the VRP do not have ICD-9-CM codes for specific identification in the Veterans Health Administration (VHA) s database. To correct this three new codes have been created. They are : Apnea, Sleep (99001), Chronic Fatigue Syndrome (CFS) (99002), and Fibromyalgia (99003). Make certain these codes are used when completing the Persian Gulf Registry (PGR) code sheets for patients who have these diagnoses. As a result of inadequate coding designations, there has been confusion between the symptoms (complaints) and diagnoses listed on the PGR code sheets. Example one: Arthralgia (diagnostic code 7194) has been used for the symptom "pain in the joint," where the symptom code 7819 (other symptoms involving nervous and musculoskeletal systems) would be more appropriate. Example two: Symptom ICD-9-CM code 78051 has been designated for insomnia with sleep apnea; however, sleep apnea is more correctly identified as a specific diagnosis which has the new code 99001. Symptom code 78051 may still be used for insomnia with sleep apnea. Example three: Symptom ICD-9-CM code 7807 has been used to designate CFS and the symptoms of malaise and fatigue. The new code 99002 has been determined for CFS, so ICD-9-CM code 7807 should be used for medical complaints of malaise and fatigue

<u>DIAGNOSIS</u>	<u>ICD-9-CM Code</u>
(1) Amebiasis	006
(2) Apnea, sleep	99001
(3) Arthralgia	7194
(4) Asthma	493
(5) Brill's Zinsser disease (recrudescence typhus)	0811
(6) Bronchiectasis	494
(7) Bronchopneumonia, organism unspecified	485
(8) Brucellosis	023
(9) Chronic obstructive pulmonary disease, not elsewhere classified	496
(10) Chronic bronchitis	491
(11) Chronic Fatigue Syndrome	99002
(12) Chronic laryngotracheitis	4761
(13) Chronic respiratory conditions due to fumes and vapors	5064
(14) Emphysema	492
(15) Fibromyalgia	99003
(16) Giardiasis	0071
(17) Leishmaniasis	085
(18) Malaria	084
(19) Other and unspecified diseases of upper respiratory tract	4789
(20) Pneumoconiosis due to other silica or silicates	502
(21) Pneumoconiosis, unspecified	505
(22) Unspecified chronic respiratory disease	5199
(23) Respiratory conditions due to unspecified external agent	5089
(24) Sandfly fever (phlebotomus fever)	0660

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<u>DIAGNOSIS</u>	<u>ICD-9-CM CODE</u>
(25) Schistosomiasis (bilharziasis)	120
(26) Toxoplasmosis	130
(27) Typhoid fever, also carrier - V02.1	0020
(28) Tuberculosis, specify variant(s)	010-018
(29) Viral hepatitis	070
(30) Memory loss	310
(31) Polyneuropathy	356-357
(32) Skin rash	680-709
(33) Adjustment disorder, including Post Traumatic Stress Disorder (PTSD)	309
(34) Alcohol dependence syndrome	303
(35) Drug dependence	304

4. In gathering these data, it is important to determine and record the:

- a. Time of onset of the symptoms or conditions,
- b. Intensity,
- c. Degree of physical incapacitation, and
- d. Details of any treatment received.

5. Each veteran's spouse or child will be given the following baseline laboratory studies (Phase I Registry Examination): *NOTE: As a routine children should not be subjected to laboratory studies such as complete blood count (CBC), electrolyte glucose or equivalent blood chemistries and enzyme studies. Diagnostic testing should only be performed as judged medically necessary by the examining physician.*

- a. CBC;
- b. Electrolyte Glucose (SMA-6, SMA-12), or equivalent blood chemistries and enzyme studies; and
- c. Urinalysis.

6. Appropriate additional diagnostic studies should be performed and consultations obtained as indicated by the patient's symptoms and the physical and laboratory findings. *NOTE: If individuals have unexplained illnesses, a Phase II examination is recommended after Phase I registry examination is completed.*

- a. Other diagnostic studies, such as pulmonary function test, pap smear, sperm counts, should be performed as medically indicated.
- b. Laboratory tests results will be provided to VA for filing in the CHR.

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**SAMPLE AND INSTRUCTIONS FOR COMPLETING VA FORM 10-9009c, PERSIAN GULF REGISTRY
 CODE SHEET, PART I AND PART II REGISTRY EXAMINATION PHASE I, FOR SPOUSE OR
 CHILDREN OF PERSIAN GULF VETERAN**

1. General Instructions for completing VA Form 10-9009c for spouses and children.

a. An original code sheet should be prepared by the non-VA physician (Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.)), or designee, and submitted to the Veterans' Registry Coordinator (VRC), at a local Department of Veterans Affairs (VA) facility. The VRC and Veterans' Registry Physician (VRP) will review the document, and submit the ORIGINAL CODE SHEET to the Office of Financial Management Austin Automation Center (AAC) in accordance with instructions for the initial and first follow-up examinations (if clinically indicated). After code sheet data has been reviewed and entered into the computerized database at AAC, AAC staff will forward the code sheets to:

Senior Registry Coordinator (131)
 Department of Veterans Affairs
 810 Vermont Avenue, N.W.
 Washington, DC 20420.

NOTE: *These code sheets will not be returned to the medical center of origin unless corrections are required.*

(1) A legible copy of the code sheet will be filed in the PGW veteran's medical record with any corrections required by AAC. Additional follow-up examinations, as provided by the private physician, as clinically indicated, can be submitted for inclusion in veteran's Consolidated Health Record (CHR).

(2) A code sheet for additional follow-up examinations need not be prepared or submitted to the AAC except when a diagnosis and diagnostic code differs from previously submitted code sheets. For any diagnostic change, a code sheet will be prepared and submitted for entry into the Persian Gulf Registry III (PGR III).

b. The non-VA licensed physician, or designee, should complete this form using the following marking instructions:

(1) PRINT CLEARLY USING A NO. 2 PENCIL OR BLUE OR BLACK INK PEN ONLY.

(2) DO NOT USE PENS WITH INK THAT SOAK THROUGH THE PAPER.

(3) MAKE SOLID MARKS THAT FILL OVALS COMPLETELY.

(4) COMPLETE ALL HORIZONTAL GRIDS IN ACCORDANCE WITH EXAMPLE SHOWN ON UPPER RIGHT HAND SIDE OF PAGE 1, OF CODE SHEET.

(5) WHERE BLOCKS ARE INDICATED AND/OR NUMBERED; E.G., 2-117, ENTER ONE LETTER OR NUMBER PER BLOCK. VETERAN AND PRIVATE PHYSICIAN SHOULD BE AWARE THAT THE NUMERIC ZERO MUST BE SLASHED "Ø."

(6) MAKE NO STRAY MARKS ON THIS FORM.

(7) DO NOT FOLD, TEAR, OR MULTILATE THIS FORM.

(8) FOLLOW INSTRUCTIONS CAREFULLY TO ENSURE THAT ALL DATA FIELDS ARE COMPLETED ACCURATELY.

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c. For registry coding purposes, VA coding clerks should use the International Classification of Diseases - Clinical Modification, 9th Edition, (ICD-9-CM) codes. These must be the codes currently in use by AAC.

(1) Part I of the code sheet should be completed by the non-VA physician (M.D. or D.O.) during the medical history taken from veteran's spouse or in the case of a child, by one of the parents.

(2) Parts II and III of the code sheet should be completed at the time of the examination by the licensed non VA-physician (M.D. or D.O.) Completed Parts I, II and III will be returned to VRC at the local VA facility for review and assignment of the ICD-9-CM codes in appropriate blocks. *NOTE: VA coders should pay careful attention to assigning the correct code for both complaints (symptoms) and diagnosis. ICD-9 CM code 78999, for uncodable complaints (symptoms), should be assigned only after all coding possibilities have been thoroughly explored. The indiscriminate use of 78999 may result in skewed or misleading statistics of minimal value.*

(3) Date all code sheets with current date in the upper right hand corner of VA Form 10-9009c.

2. Instructions for Completing Part I (Initial Examination)

a. **Item 1. Blocks 2-7. Facility Number and Suffix.** VA coders are to enter facility code as listed in MP-6, Part XVI, Supplement No. 4.1, Appendix A. Use the AMIS suffix (BY, BZ, etc.) to indicate your satellite facility. **DO NOT USE Q, R, OR S.** *NOTE: If spouse or child requests the inclusion of Department of Defense (DOD) registry examination records in VA PGR, submit code sheet with Facility Number as 999 in Blocks 2, 3 and 4 and indicate actual VA facility number in upper left margin of code sheet.*

b. **Item 2. Blocks 8-33. Last Name of Spouse or Child.** Beginning in Block 8, enter spouse's or child's current last name. Do not use apostrophe and/or hyphen in the name or skip blocks between the letters of the last name. Skip a block if the last name is followed with Jr., Sr., I, II, III, etc.

c. **Item 3. Blocks 34-48. First Name of Spouse or Child.** Beginning in Block 34, enter spouse's or child's first name.

d. **Item 4. Blocks 49-58. Middle Name of Spouse or Child.** Beginning Block 49, enter spouse's or child's middle name or initial.

e. **Item 5. Block 59. Type of Examination.** The following transaction type should be entered in Block 59 as appropriate:

A - Initial examination. Spouse's or Child's first Persian Gulf examination.

B - To delete an entire initial examination with a noted error, after it has been accepted into the registry, resubmit the original code sheet with a "B" and submit another code sheet with the correct information with an "A." All fields must be completed on a resubmission. VA staff can submit the code sheets to AAC in the same batch. Examples of this usage are incorrect diagnosis, military statistics, Social Security Number (SSN), etc.

C - Follow-up examination. Second Persian Gulf examination. Additional follow-up examinations, as clinically indicated, will require an additional code sheet only if a new diagnosis is determined. VA staff will submit this code sheet to AAC for entry into PGR III.

D - To delete an entire follow-up PGR III examination with a noted error, after it has been accepted into the registry, resubmit the original code sheet with a "D" and submit another code sheet with the correct information with a "C."

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E - To submit changes in demographics, i.e., change of address or date of birth enter "E" and complete items with name, SSN, date of birth, and address. No other items need to be completed.

X - When a registry participant has been identified and verified as being deceased, enter "X." Complete items with name, SSN, and date of birth. No other items need to be completed.

f. Item 6. SSN. The first shaded block is to be used ONLY if a pseudo SSN is being submitted. In this event, the letter "P" will be entered in this block. Leave this shaded block blank when the actual SSN is used. Beginning in numbered rows enter the actual SSN, or pseudo SSN by using solid marks to completely fill each appropriate numbered oval. (VA Coders see M-1, Pt. I, Ch. 5, par. 5.29, for instructions regarding a pseudo SSN assignment.) *NOTE: All efforts should be made to obtain actual SSN.*

g. Item 7. Blocks 60-65. Date of Birth. Beginning in Block 60 enter numerical equivalent for the month, day and year in that order (e.g., 01/19/50). All blocks must be completed.

h. Item 8. Blocks 66-131. Permanent address

(1) Blocks 66-91. Beginning in Block 66 enter permanent street address.

(2) Blocks 92-117. Beginning in block 92 enter city or town.

(3) Blocks 118-122. Enter zip code of permanent residence (National Zip Code Directory).

(4) Blocks 123-126. Leave Blank (future extended Zip Code).

(5) Blocks 127-129. VA coders will enter appropriate county code as listed in VHA M-1, Part I, Chapter 18, Appendix A.

(6) Blocks 130-131. VA coders will enter appropriate state code as listed in VHA M-1, Part I, Chapter 18, Appendix A.

i. Item 9. Race/Ethnicity. Make solid mark in correct oval block on code sheet using one of the following options:

- () = American Indian or Alaskan Native
- () = Asian or Pacific Islander
- () = Black, not of Hispanic Origin
- () = White, not of Hispanic Origin
- () = Hispanic
- () = Unknown

j. Item 10. Marital Status. Make solid mark in correct oval on code sheet to indicate marital status, using one of the following options:

- () = Married
- () = Divorced
- () = Separated
- () = Widowed
- () = Not Applicable (Child)

k. Item 11. Sex. Make solid mark to fill correct oval on code sheet to indicate sex, using one of the following options:

- () = Male
- () = Female

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l. **Item 12. Relationship to Veteran:** Make solid mark to fill correct oval on code sheet to indicate one of the following:

- () = Spouse
- () = Child

m. **Items 13, 13A-F. Smoking History:** Mark appropriate ovals on code sheet:

(1) **Item 13A.** Are you currently smoking cigarettes? Make a solid mark to fill correct oval on code sheet:

- () = Yes
- () = No

NOTE: If no, go to Item 13D.

(2) **Item 13B.** If yes, how many years have you been smoking cigarettes? Enter number of years in horizontal grid, filling number in left hand block(s) and using a solid mark to fill the appropriate numbered oval(s) on code sheet (see example in upper right hand corner of page 1 of code sheet).

(3) **Item 13C.** If yes, on the average, how many packs are you smoking per day? Enter the number of packs in horizontal grid, filling number in left hand block(s) and using a solid mark to fill the appropriate numbered oval(s) on code sheet.

(4) **Item 13D.** Have you smoked cigarettes in the past? Use a solid mark to fill the appropriate oval on code sheet, using the following options:

- () = Yes
- () = No.

NOTE: If no, go to Item 14.

(5) **Item 13E.** If yes, how many years did you smoke? Enter number of years in the horizontal grid, filling number in left hand block(s) and using a solid mark to fill the appropriate numbered oval(s) on code sheet.

(6) **Item 13F.** If yes, on the average how many packs did you smoke per day? Enter number of packs in the horizontal grid, filling number in left hand block(s) and using a solid mark to fill by marking the appropriate numbered ovals on code sheet.

n. **Item 14. Have you had contact with or experienced any of the following?**

(1) **Item 14A.** Did you come in contact with any military equipment that the Persian Gulf veteran brought back from the Gulf War; e.g., helmets, canteens, armaments? Enter "Yes" or "No" by making a solid mark to fill the correct oval on the code sheet.

- () = Yes
- () = No

(2) **Item 14B.** During intercourse with your Persian Gulf spouse, do you experience vaginal or skin burning after he ejaculates or "comes?" Enter "Yes" or "No" by making a solid mark to fill the correct oval on the code sheet.

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- () = Yes
() = No

NOTE: Since this question is directed to a female spouse, no response is required of a male spouse or a child.

(3) **Item 14C.** Do you believe your health problems are related to the veteran's Persian Gulf service? Enter "Yes" or "No" by making a solid mark to fill the correct oval on the code sheet.

- () = Yes
() = No

o. Item 15. Spouse or Child's Health Evaluation. Make a solid mark to fill the correct oval on the code sheet, using the following options which best describes the spouses' or child's health after veteran's Persian Gulf Service:

- () = Very good
() = Good
() = Fair
() = Poor
() = Very poor

p. Item 16. Spouse or Child's Functional Impairment.

(1) **Item 16A.** Make a solid mark to fill the correct oval on the code sheet which describes spouse's or parents' assessment of child's functional impairment, after Persian Gulf Service, using the following scale:

- () = No impairment
() = Slight impairment
() = Moderate impairment
() = Severe impairment

(2) **Item 16B.** Is spouse employed outside the home? Make a solid mark to fill the correct oval on the code sheet, using one of the following options:

- () = Yes
() = No

(3) **Item 16C.** If spouse is employed outside the home, how many workdays were lost by spouse due to illness? Enter the number of workdays in horizontal grid, filling number in left hand block(s) and make a solid mark to fill the correct oval on the code sheet.

NOTE: If none, enter 0s, and go to Item 17.

q. Item 17. Evidence of Birth Defects and Infant Death(s) among veteran's children and problems with pregnancy.

(1) **Item 17A.** How many children does veteran have? Enter the number of children in horizontal grid, filling number in left hand blocks(s) and make a solid mark to fill the correct oval on the code sheet.

NOTE: If none, enter 0, and go to Item 17C.

(2) **Item 17B. Birth Defects.** **NOTE:** Birth defects are any structural, functional, or biochemical abnormality at birth whether genetically determined or induced during gestation that is not due to injuries suffered during birth. How many of these children were born with birth defects? Enter the number of

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children in horizontal grid, filling number in left hand block(s) and make a solid mark to fill the correct oval on the code sheet.

NOTE: If none, enter 0s, and go to Item 17C.

(a) Item 17B1. How many of these children with birth defects were conceived before Gulf service? Enter the number of children with birth defects, in horizontal grid, filling number in left hand block(s) and make a solid mark to fill the correct oval on the code sheet.

NOTE: If none, enter 0s and go to Item 17B2.

(b) Item 17B1(a). State maternal age at conception of first child with birth defects, conceived before Gulf service. Enter age in horizontal grid, filling number in left hand block(s) and make a solid mark to fill the correct oval on the code sheet.

(c) Item 17B2. How many of these children with birth defects, were conceived during and after Gulf service? Enter the number of children with birth defects, in horizontal grid, filling number in left hand block(s) and make a solid mark to fill the correct oval on the code sheet.

NOTE: If none, enter 0s and go to Item 17C.

(d) Item 17B2(a). State maternal age at conception of first child with birth defects, conceived during and after Gulf service. Enter age in horizontal grid, filling number in left hand block(s) and make a solid mark to fill the correct oval on the code sheet.

(3) Item 17C. Infertility, i.e., problems of veteran or spouse becoming pregnant. **NOTE:** Infertility=relative sterility defined as inability to conceive after 12 or more months of intercourse without use of contraception when neither spouse is surgically sterilized. Has veteran or spouse had infertility problems? Make a solid mark to fill the correct oval on the code sheet, using one of the following options:

- () = Yes
() = No

NOTE: If no, go to Item 17D.

(a) Item 17C1. Has veteran or spouse had infertility before Gulf service? Make a solid mark to fill the correct oval on the code sheet, using one of the following options:

- () = Yes
() = No

NOTE: If no, go to Item 17C2.

(b) Item 17C1(a). State maternal age during first attempts to conceive. Enter the age in horizontal grid, filling number in left hand block(s) and make a solid mark to fill the correct oval on the code sheet.

(c) Item 17C2. Has veteran or spouse had infertility after return from Gulf service? Make a solid mark to fill the correct oval on the code sheet, using one of the following options:

- () = Yes
() = No

NOTE: If no, go to Item 17D.

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(d) Item 17C2(a). State maternal age during first attempts to conceive. Enter the age in horizontal grid, filling number in left hand block(s) and make solid mark to fill correct oval on code sheet.

(4) Item 17D. Provide information on all of spouse's pregnancies. For multiple outcomes, make a separate entry for each (e.g., two entries for twins). If there is uncertainty about details, provide best estimate.

(a) Items 17D1-D8. Lists first through eighth pregnancy. Complete appropriate adjoining column; e.g., "Outcomes," which lists one "Normal Live Birth" and five reproductive health problems, as follows:

1. Normal Live Birth.
2. Live Birth with Birth Defects.
3. Still Birth. *NOTE: Still births are births after 20 weeks of gestation of an infant who showed no evidence of life after birth.*
4. Miscarriage(s). *NOTE: A miscarriage is a spontaneous expulsion of the products of conception before 20 weeks of gestation (spontaneous abortion).*
5. Infant Death(s). Death that occurred within 1 year of birth among babies born alive.
6. Ectopic Pregnancy(ies). *NOTE: An ectopic pregnancy is gestation (conception) outside of the uterus.*

NOTE: Make make solid mark to fill correct oval on code sheet. Leave blank if they do not apply.

(b) Items 17D1-D8: Date of Outcome. Enter month by filling in ovals; day and year of outcome by filling in blocks and ovals on grid.

(c) Item 17D1-D8: Length of Pregnancy. Enter months or weeks of pregnancy by filling in blocks and ovals on grid.

3. Instructions for Completing PGR III code sheet, Part II (Initial Examination). *NOTE: This part must be completed by the examining non-VA physician (M.D. or D.O.). This protocol constitutes a set of clinical practice guidelines for the evaluation of individuals with unexplained illnesses after their service, or their spouse's/parent's military service, in the Persian Gulf. As such, these guidelines should be utilized with a high degree of medical judgment dependent on numerous factors such as type and severity of complaints, general health status, age, etc. After completion of the relevant portions of the protocol the non-VA physician (M.D. or D.O.) should complete the code sheet in the following manner:*

a. Item 18. Date of Examination. Enter Month, Day and Year of examination - make solid mark to fill correct oval for month, day and year and complete blocks for day and year in vertical grid on code sheet.

b. Item 19. Total Number of Spouse or Child's Complaints. Enter total number of examinee's complaints in upper blocks of vertical grid and make a solid mark to fill each correct oval in vertical grid of code sheet.

c. Item 20, 20A-K. Spouse or Child's Complaints, Month and Year of Onset, Duration in Months, whether Symptom is Currently Present, and Most Severe Complaint.

(1) Item 20A-J. Grid Columns: (1) Spouse or Child's Complaints/Symptoms; (2) ICD-9-CM codes (VA coders will enter these codes); (3) Month and Year of Onset; (4) Duration in months; and (5) State whether symptom is still present. List up to ten major and current symptoms/complaints. If PGW veteran's spouse or child has more than 10, enter most severe. Any additional symptoms should be listed in Persian Gulf Veteran's Consolidated Health Record (CHR). *NOTE: MAS coders use ICD-9-CM*

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"Symptom" codes in first five numbered blocks of each line. For uncodable symptoms use "78999." For no known complaints, use "78000." However, 78999 should ONLY be used if all possible codes have been reviewed, and if necessary, seek physician consultation to make a correct choice.

(2) Item 20A-J(1). Give a narrative description clearly and concisely of ten major, current symptoms as stated by spouse or child (parent). Indicate on first line (20A1) the symptom/complaint which the veteran's spouse or child (parent) considers the most severe.

(3) Item 20A-J(2). VA MAS coders are to complete the ICD-9-CM codes as they relate to each symptom. VA MAS coders will make a solid mark to fill correct oval and fill in ICD-9-CM codes in upper blocks of grid on code sheets.

(4) Item 20A-J(3). For each symptom listed in 22A-J, on code sheets provide month and year of onset by making a solid mark to fill correct oval for month and year of onset and filling in the two upper blocks of grid with the year of onset; i.e., 96.

(5) Item 20A-J(4). For each symptom listed in 22A-J, state duration in months that veteran's spouse or child has been experiencing this symptom. On code sheet indicate month by making a solid mark to fill correct oval and two upper blocks of grid.

(6) Item 20A-J(5). For each symptom listed in 22A-J, indicate if symptom is currently present, make a solid mark to fill correct oval, using one of the following options:

- () = Yes
- () = No

(7) Item 20K. Most Severe Symptom/Complaint. Non-VA physician should provide in concise, clear narrative form the most severe symptom (Line 20A1). VA coders will provide related ICD-9 code by making a solid mark to fill correct ovals and list ICD-9-CM codes in upper blocks of grid on code sheet.

d. Item 21, A-S. Diagnostic workup/consultation. On code sheet enter one of the following codes in the ovals on the grid for each consultation listed in Items A-Q. All items must be completed.

- 1 = No workup. No consultation done.
- 2 = Workup/consultation done. Unexplained illness.
- 3 = Workup/consultation done. Diagnosis established.
- 4 = Workup/consultation done. No diagnosis.

- (1) Item 21A. Allergy/Immunology.
- (2) Item 21B. Audiology.
- (3) Item 21C. Cardiology.
- (4) Item 21D. Dentistry.
- (5) Item 21E. Dermatology.
- (6) Item 21F. Ear, Nose, and Throat.
- (7) Item 21G. Endocrinology.
- (8) Item 21H. Gastroenterology.
- (9) Item 21I. Hematology/Oncology.

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- (10) Item 21J. Infectious Diseases/Parasitology.
- (11) Item 21K. Nephrology.
- (12) Item 21L. Neurology.
- (13) Item 21M. Occupational Medicine.
- (14) Item 21N. Pulmonary.
- (15) Item 21O. Psychiatry.
- (16) Item 21P. Psychology/Psychometric Testing.
- (17) Item 21Q. Rheumatology.
- (18) Item 21R. Other. Were any additional workups/consultations performed as part of Persian Gulf examination which were not listed in Items 21A-Q. On the code sheet make a solid mark to fill one of the ovals, using one of the following options:
 () = Yes
 () = No
- (19) Item 21S. Specify on code sheet and CHR, in narrative form, clearly and concisely, any additional workups/consultations performed as part of Persian Gulf examination, which were not listed in Item 21A-Q.

e. Item 22, 22A-J. Diagnoses

(1) Item 22A-J. The non-VA physician (M.D. or D.O.) will list up to 10 major definite medical diagnoses in narrative form, clearly and concisely, on lines 22A-J, with the primary diagnosis listed on Line A. The examining non-VA physician will select the 10 most significant/serious in diagnoses. The additional diagnosis(es) must be included in patient's (veteran's) CHR. Grid ovals and blocks are to be used by VA coders for ICD-9-CM coding of each diagnosis listed. Leave blank if no diagnosis is made. **NOTE: Diagnostic coding assignment will be completed by VA coders. DO NOT REPEAT OR LIST SYMPTOM CODE ALREADY LISTED UNDER ITEM 20A-J.**

f. **Item 23. No Diagnosis Made.** If no diagnosis is made, make a solid mark in oval on code sheet, otherwise leave oval blank. This item must be considered in conjunction with Item 22, "Diagnoses."

g. **Item 24, 24A-D. Disposition.** On code sheet make a solid mark in one of the ovals under each item (24A-D), using one of the following options:

- () = Yes
- () = No
- (1) Item 24A. Examination completed?
- (2) Item 24B. Hospitalized for further tests?
- (3) Item 24C. Hospitalized for treatment?
- (4) Item 24D. Referred for further outpatient care?

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h. Item 25. After the completion of the Phase I examination, the non-VA physician has determined that the examinee has an unexplained illness? On the code sheet make a solid mark in the oval, using one of the following options:

- () = Yes
() = No

i. Item 26. Has Phase II (Uniform Case Assessment Protocol) examination been initiated? On code sheet, make a solid mark in the oval, using one of the following options:

- () = Yes
() = No

j. Item 27. P.G. Veteran's Last Name: On code sheet print veteran's current last name.

k. Item 28. First Name of PGW Veteran. On code sheet print veteran's first name.

m. Item 29. Middle Initial of PGW Veteran. On code sheet print veteran's middle initial.

k. Item 30. PGW Veteran's SSN: On code sheet the first shaded block is to be used ONLY if a pseudo is being submitted. In this event, the letter "P" will be entered in this block. Leave this first block blank when the actual SSN is used. Beginning in second block, enter the actual SSN, or pseudo SSN. (VA coders see M-1, Pt. I, Ch. 5, par. 5.29, for instructions regarding SSN assignment.) In addition to the SSN appearing in the horizontal blocks of this grid, make a solid mark in the correct oval to designate the SSN. **NOTE: All efforts should be made to obtain actual SSN.**

n. Item 31. Remarks. Utilize this section for any additional information pertinent to this examination.

o. Item 32. Name of Examiner. Print full name.

p. Item 33. Title of Examiner. Full title of Examiner.

q. Item 34. Signature of Examiner. Signature of individual who conducted examination.

r. Item 35. Signature of Physician (if other than Examiner). A physician's countersignature is necessary if examiner is other than a physician (physician's assistant or nurse practitioner).

4. Follow-up Examinations. Instructions for completing Parts I and II. In addition to initial registry submissions, VA Form 10-9009c, Parts I, II and III (if applicable) must be completed in reporting the first follow-up examination, and subsequent follow-up examinations if diagnostic code is different from previous examinations as follows:

- a. Items 1-12 must be completed - Control Data.
- b. Items 13-17 require no entry.
- c. Items 18-20 must be completed.
- d. Item 21 may be blank unless you have follow-up data to report in any of these items.
- e. Item 22-35 must be completed.

SAMPLE OF COMPLETED VA FORM 10-9009c, PART I, II

Department of Veterans Affairs

PERSIAN GULF REGISTRY CODE SHEET (SPOUSE OR CHILD OF PERSIAN GULF WAR VETERAN)		TT #1	1. Use PTF Number Only	FACILITY NO. 4 9 9	SUFFIX DA 1 1 19
PART I (Phase I)					
The information the veteran supplies may be disclosed outside the VA to Federal, State and local government agencies and National Health Organizations to assist in the development of programs for research purposes and other uses as stated in the "Notice of Systems of VA Records" published in the Federal Register in accordance with the Privacy Act of 1974.					
INSTRUCTIONS: Persons print. Use only one letter or number per block. If possible use black ballpoint. Shaded areas for VA use only.					
2. LAST NAME (B-33) JONES					
3. FIRST NAME (34-48) JANICE					
4. MIDDLE NAME (49-58) ANN E					
5. TYPE OF SERVICE A					
6. SOCIAL SECURITY NUMBER 0111031111					
7. D.O.B. (Complete all blanks) - MO DAY YR CITY STATE ZIP 01 24 712					
8. ADDRESS (Street Name and Apartment Number, if applicable) (66-91) 44 ELIZABETH ST					
9A. CITY OR TOWN (92-117) MOBILE					
9B. COUNTY MOBILE					
9C. ZIP CODE (118-122) AL 24688					
9D. LEAVE BLANK (123-128) 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 6					

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17. (CONTINUED)

17D. Please provide information on all spouse's pregnancies. For multiple outcomes, make a separate entry for each (e.g., 2 entries for twins). If there is uncertainty about details, please provide best estimate. Items 17D1-17D8 list 1st through 8th pregnancies. "Outcomes" lists five reproductive health problems:

MISCARRIAGE(S)—A miscarriage is a spontaneous expulsion of the products of conception before 20 weeks of gestation (spontaneous abortion).

STILTBIRTH(S)—Stillbirths are births after 20 weeks of gestation of an infant who showed no evidence of life after birth.

INFANT DEATH(S)—Death that occurred within 1 year of birth among babies born alive.

ECTOPIC PREGNANCY(IES)—An ectopic pregnancy is gestation (conception) outside of the uterus.

Make a solid mark in those applicable areas. If pregnancies resulted in any of these outcomes, fill in the date of outcome and length of pregnancy in the respective areas.

17D1. FIRST PREGNANCY

OUTCOMES	DATE OF OUTCOME			LENGTH OF PREGNANCY	
	MONTH	DAY	YEAR	Months	Weeks
☒ Normal live birth	Jan	07	89	08	
☐ Live birth with birth defects	Feb				
☐ Miscarriage	Mar				
☐ Stillbirth	Apr				
☐ Infant death	May				
☐ Ectopic Pregnancy	June				
	July				
	Aug				
	Sept				
	Oct				
	Nov				
	Dec				

17D5. FIFTH PREGNANCY

OUTCOMES	DATE OF OUTCOME			LENGTH OF PREGNANCY	
	MONTH	DAY	YEAR	Months	Weeks
☐ Normal live birth	Jan				
☐ Live birth with birth defects	Feb				
☐ Miscarriage	Mar				
☐ Stillbirth	Apr				
☐ Infant death	May				
☐ Ectopic Pregnancy	June				
	July				
	Aug				
	Sept				
	Oct				
	Nov				
	Dec				

17D2. SECOND PREGNANCY

OUTCOMES	DATE OF OUTCOME			LENGTH OF PREGNANCY	
	MONTH	DAY	YEAR	Months	Weeks
☐ Normal live birth	Jan	07	90	08	
☒ Live birth with birth defects	Feb				
☐ Miscarriage	Mar				
☐ Stillbirth	Apr				
☐ Infant death	May				
☐ Ectopic Pregnancy	June				
	July				
	Aug				
	Sept				
	Oct				
	Nov				
	Dec				

17D6. SIXTH PREGNANCY

OUTCOMES	DATE OF OUTCOME			LENGTH OF PREGNANCY	
	MONTH	DAY	YEAR	Months	Weeks
☐ Normal live birth	Jan				
☐ Live birth with birth defects	Feb				
☐ Miscarriage	Mar				
☐ Stillbirth	Apr				
☐ Infant death	May				
☐ Ectopic Pregnancy	June				
	July				
	Aug				
	Sept				
	Oct				
	Nov				
	Dec				

17D3. THIRD PREGNANCY

OUTCOMES	DATE OF OUTCOME			LENGTH OF PREGNANCY	
	MONTH	DAY	YEAR	Months	Weeks
☐ Normal live birth	Jan				
☐ Live birth with birth defects	Feb				
☐ Miscarriage	Mar				
☐ Stillbirth	Apr				
☐ Infant death	May				
☐ Ectopic Pregnancy	June				
	July				
	Aug				
	Sept				
	Oct				
	Nov				
	Dec				

17D7. SEVENTH PREGNANCY

OUTCOMES	DATE OF OUTCOME			LENGTH OF PREGNANCY	
	MONTH	DAY	YEAR	Months	Weeks
☐ Normal live birth	Jan				
☐ Live birth with birth defects	Feb				
☐ Miscarriage	Mar				
☐ Stillbirth	Apr				
☐ Infant death	May				
☐ Ectopic Pregnancy	June				
	July				
	Aug				
	Sept				
	Oct				
	Nov				
	Dec				

17D4. FOURTH PREGNANCY

OUTCOMES	DATE OF OUTCOME			LENGTH OF PREGNANCY	
	MONTH	DAY	YEAR	Months	Weeks
☐ Normal live birth	Jan				
☐ Live birth with birth defects	Feb				
☐ Miscarriage	Mar				
☐ Stillbirth	Apr				
☐ Infant death	May				
☐ Ectopic Pregnancy	June				
	July				
	Aug				
	Sept				
	Oct				
	Nov				
	Dec				

17D8. EIGHTH PREGNANCY

OUTCOMES	DATE OF OUTCOME			LENGTH OF PREGNANCY	
	MONTH	DAY	YEAR	Months	Weeks
☐ Normal live birth	Jan				
☐ Live birth with birth defects	Feb				
☐ Miscarriage	Mar				
☐ Stillbirth	Apr				
☐ Infant death	May				
☐ Ectopic Pregnancy	June				
	July				
	Aug				
	Sept				
	Oct				
	Nov				
	Dec				

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20A-I. (CONTINUED)

18. DATE OF EXAM

MONTH	DAY	YEAR
☐ Jan		
☐ Feb		
☐ Mar		
☐ Apr		
☐ May		
☐ June		
☐ July		
☐ Aug		
☐ Sept		
☐ Oct		
☐ Nov		
☐ Dec		

19. TOTAL NUMBER OF THE EXAMINEE'S COMPLAINTS
16

20A-J. LIST UP TO TEN MAJOR, CURRENT SYMPTOMS, ICD 9 CODES, MONTH AND YEAR OF ONSET, DURATION IN MONTHS AND IF SYMPTOM IS CURRENTLY PRESENT ON GRIDS A-J, ITEMS 1-5. IF EXAMINEE HAS MORE THAN 10, ENTER THE MOST SEVERE AND ADDITIONAL SYMPTOMS IN CHR. MAS CODERS: USE ITEM 2, FOR ICD-9-CM CODES.

20A. 1. Describe symptom: FATIGUE
2. ICD-9-codes: 780.29
3. Month and year of onset: Jan 92
4. Duration (months): 12
5. Currently present? ☒ Yes ☐ No

20B. 1. Describe symptom: HEADACHE
2. ICD-9-codes: 784.0
3. Month and year of onset: Jan 92
4. Duration (months): 12
5. Currently present? ☒ Yes ☐ No

20C. 1. Describe symptom: DIZZINESS
2. ICD-9-codes: 780.4
3. Month and year of onset: Jan 92
4. Duration (months): 12
5. Currently present? ☒ Yes ☐ No

20D. 1. Describe symptom: SLEEP DISTURBANCE
2. ICD-9-codes: 780.49
3. Month and year of onset: Jan 92
4. Duration (months): 12
5. Currently present? ☒ Yes ☐ No

20E. 1. Describe symptom: COUGH
2. ICD-9-codes: 786.2
3. Month and year of onset: Jan 92
4. Duration (months): 12
5. Currently present? ☒ Yes ☐ No

20F. 1. Describe symptom: JOINT PAIN
2. ICD-9-codes: 780.91
3. Month and year of onset: Jan 92
4. Duration (months): 12
5. Currently present? ☒ Yes ☐ No

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20A-1. (CONTINUED)

20G.

1. Describe symptom

2. ICD-9-codes

3. Month and year of onset

4. Duration (months)

5. Currently present? ☐ Yes ☐ No

20H.

1. Describe symptom

2. ICD-9-codes

3. Month and year of onset

4. Duration (months)

5. Currently present? ☐ Yes ☐ No

20I.

1. Describe symptom

2. ICD-9-codes

3. Month and year of onset

4. Duration (months)

5. Currently present? ☐ Yes ☐ No

20J.

1. Describe symptom

2. ICD-9-codes

3. Month and year of onset

4. Duration (months)

5. Currently present? ☐ Yes ☐ No

20K. List most severe symptom. (A symptom from items A-J, which veteran's spouse or child (parent) considers the most severe, i.e., chief complaint.) Enter ICD-9-CM code and describe symptom.

Describe symptom

ICD-9-CM CODES

FATIGUE

7807

21. DIAGNOSTIC CONSULTATION. ENTER THE FOLLOWING CODES:

4 = WORKUP/CONSULTATION DONE, NO DIAGNOSIS.

3 = WORKUP/CONSULTATION DONE, DIAGNOSIS ESTABLISHED.

2 = WORKUP/CONSULTATION DONE, UNEXPLAINED ILLNESS.

1 = NO WORKUP, NO CONSULTATION DONE.

A. ALLERGY/IMMUNOLOGY

B. AUDIOLOGY

C. CARDIOLOGY

D. DENTISTRY

E. EENT (EAR, NOSE, AND THROAT)

F. GASTROENTEROLOGY

G. GASTROENTEROLOGY

H. GASTROENTEROLOGY

I. GASTROENTEROLOGY

J. GASTROENTEROLOGY

K. GASTROENTEROLOGY

L. GASTROENTEROLOGY

M. GASTROENTEROLOGY

N. GASTROENTEROLOGY

O. GASTROENTEROLOGY

P. GASTROENTEROLOGY

Q. GASTROENTEROLOGY

R. GASTROENTEROLOGY

S. GASTROENTEROLOGY

T. GASTROENTEROLOGY

U. GASTROENTEROLOGY

V. GASTROENTEROLOGY

W. GASTROENTEROLOGY

X. GASTROENTEROLOGY

Y. GASTROENTEROLOGY

Z. GASTROENTEROLOGY

1. OTHER ☐ Yes ☐ No

2. ADDITIONAL WORKUPS/CONSULTATIONS PERFORMED WHICH WERE NOT LISTED IN ITEMS 21A-G, LIST HERE AND IN CHL.

GYNECOLOGY CONSULT

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NAME: JONES, JANICE SSN: 011-13-1111	
24. DISPOSITION	
24A. Examination completed? ☒ Yes ☐ No	
24B. Hospitalized for further tests? ☐ Yes ☒ No	
24C. Hospitalized for treatment? ☐ Yes ☒ No	
24D. Referred for further outpatient care? ☒ Yes ☐ No	
25. AFTER COMPLETION OF PHASE I EXAM, THE PHYSICIAN HAS DETERMINED THE EXAMINEE HAS AN UNEXPLAINED ILLNESS? ☒ Yes ☐ No	
26. HAS PHASE II EXAM (UNIFORM CASE ASSESSMENT PROTOCOL, PART B) BEEN INITIATED (IF MEDICALLY INDICATED)? ☒ Yes ☐ No	
PERSIAN GULF WAR (PGW) VETERAN	
27. LAST NAME JONES	32. NAME OF EXAMINER (PRINT FULL NAME) JOHN DOE, M.D.
28. FIRST NAME JOHN	33. TITLE OF EXAMINER (FULL TITLE OF EXAMINER) PRIVATE PHYSICIAN
29. MIDDLE INITIAL E.	34. SIGNATURE OF EXAMINER John Doe M.D.
30. SOCIAL SECURITY NUMBER 011-13-1111	35. SIGNATURE OF PHYSICIAN (IF OTHER THAN EXAMINER)

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ADVANCED
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APPENDIX 5C

VA UNIFORM CASE ASSESSMENT PROTOCOL (UCAP), PHASE II

1. Phase I Level Laboratory Evaluations

- a. Complete Blood Count (CBC)
- b. Urinalysis
- c. Blood Chemistry - SMA-6

2. Phase II-Level Evaluation Protocol. Phase II Level Evaluations are recommended for those spouses or children of Persian Gulf War (PGW) veterans after complete clinically indicated evaluations are conducted and the non-VA licensed physician (Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.)) determines that the patient (spouse or child) has an unexplained illness. Individuals who after completing Phase I or Registry evaluations have disability and do not have a clearly defined diagnosis which explains their symptoms, must receive the following supplemental baseline laboratory tests and consultations.

NOTE: Diagnostic testing of children should only be performed as judged medically necessary by the examining physician.

a. Supplemental Baseline Laboratory Tests

- (1) CBC,
- (2) Sedimentation Rate Erythrocyte Sedimentation Rate (ESR),
- (3) C-Reactive Protein,
- (4) Rheumatoid Factor,
- (5) Anti-Nuclear Antibody (ANA),
- (6) Liver Function,
- (7) Creatine Phosphokinase (CPK),
- (8) Hepatitis Serology,
- (9) Human Immuno-deficiency (HIV),
- (10) Venereal Disease Research Laboratory (VDRL),
- (11) B-12 and Folate,
- (12) Thyroid Function Tests,
- (13) Urinalysis, and
- (14) Tuberculosis (TB) Skin Test Purified Protein Derivative (PPD).

b. Consultations

- (1) Dental. If clinically indicated and only if participant's annual screening is done.
- (2) Infectious Disease.

(3) Psychiatry (with physician-administered instruments):

(a) Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (DSM III-R) Third Edition, Revised, also known as SCID. Delete nodules for mania and psychosis.

(b) Clinician Administered Post Traumatic Stress Disorder (PTSD) Scale (CAPS).

(4) Neuropsychological Testing (only as indicated by psychiatry consult).

c. Symptom-specific Examination:

Individuals who have the following symptoms should have the following minimum workup.

(1) Diarrhea

(a) Gastrointestinal (GI) Consult,

(b) Stool for Ova and Parasites (O&P),

(c) Stool Leukocytes,

(d) Stool Culture,

(e) Stool Volume,

(f) Colonoscopy with biopsies, and

(g) Esophagastroduodenoscopy (EGD) with biopsies and aspiration.

(2) Abdominal pain

(a) GI Consult,

(b) EGD with biopsy and aspiration,

(c) Colonoscopy with biopsy,

(d) Abdominal Ultrasound,

(e) Upper Gastrointestinal (UGI) series with small bowel follow-through, and

(f) Abdominal Computed Tomography (CT) Scan.

(3) Headache

(a) Magnetic Resonance Imaging (MRI) of the head

(b) Lumbar Puncture (LP) to include:

1. Glucose,

2. Protein,

3. Cell Count,

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4. Venereal Disease Research Laboratory (VDRL),
5. Oligoclonal, (IgG),
6. Myelin basic protein,
7. Opening Pressure, and
8. Neurology consult.
- (4) **Muscle Aches/Numbness**
 - (a) Electromyogram (EMG) and
 - (b) Nerve Conduction Velocity (NCV).
- (5) **Memory Loss (only if verified by neuropsychological testing)**
 - (a) Magnetic Resonance Imaging (MRI),
 - (b) Lumbar Puncture (LP), (see tests on headache evaluation, subpar (3),
 - (c) Neurology Consult, and
 - (d) Neuro-psychological Testing.
- (6) **Vertigo/Tinnitus**
 - (a) Audiogram,
 - (b) Electronystamogram (ENG), and
 - (c) Brainstem Auditory Evoked Response (BAER).
- (7) **Chronic Fatigue**
 - (a) Polysomnography, and
 - (b) Multiple Sleep Latency Test (MSLT).
- (8) **Chronic Cough/Shortness of Breath**
 - (a) Pulmonary Consult,
 - (b) Pulmonary Function Test (PFT) with exercise and Arterial Blood Gases (ABG),
 - (c) If routine PFT's are negative, perform Methacholine challenge test, and
 - (d) Bronchoscopy with biopsy/lavage (to be considered if PFTs are normal).
- (9) **Chest Pain/Palpitations**
 - (a) Electrocardiogram (ECG),

- (c) Holter Monitor.
 - (10) Skin Rash
 - (a) Dermatology Consult, and
 - (b) Consider biopsy.
 - (11) Reproductive Concerns
 - (a) Males -Urology consult, and
 - (b) Females - Gynecology (GYN) consult.
- (c) Additional elements recommended for the evaluation of spouses and children of PGW veterans with complaints of Reproductive Health Problems (RHP):
1. Detailed genitourinary history and problems as follows:
 - a. Sexual,
 - b. Genitourinary symptoms,
 - c. Menstrual,
 - d. Contraceptive practices,
 - e. Pregnancy-related,
 - f. Conception,
 - g. Birth defects,
 - h. Congenital disorders,
 - i. Menopause,
 - j. Prior infections,
 - k. Prior surgery, and
 - l. Exposures to toxic agents, etc.
 2. Detailed genital and/or pelvic examination.
 3. Laboratory and ancillary testing, to include:
 - a. Pap tests; and
 - b. Tests for genitourinary infections.
 4. Urologist consultation for male veterans who have RHP that cannot be diagnosed or managed successfully by primary care practitioners.

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4. Urologist consultation for male veterans who have RHP that cannot be diagnosed or managed successfully by primary care practitioners.

Gynecology consultation for female veterans who have RHP that cannot be diagnosed or managed successfully by primary care practitioners.

(d) Additional elements for evaluation of spouses of PGW veterans with complaints of infertility.

1. Detailed menstrual and reproductive history (such as the Infertility Questionnaire utilized by Walter Reed Army Medical Center).

2. Semen analysis, to include:

a. Volume,

b. pH,

c. Liquefaction,

d. Sperm concentration,

e. Motility,

f. Progressive motility,

g. Sperm viability,

h. Leukocytes, and

i. Morphology.

3. Referral to an infertility specialist or program.

(e) Additional elements for evaluation of PGW veteran's spouses and/or children with complaints related to birth defects or genetic disorders in offspring conceived during or after PGW service.

1. Detailed history of congenital or genetic disorders (such as the Patient Genetic Screen Questionnaire utilized by Walter Reed Army Medical Center).

2. Detailed occupational exposures questionnaire (such as Worker and Supervisor Questionnaires utilized by National Naval Medical Center).

NOTE: For copies of these questionnaires (Items (d)1., (e) 1., and 2. contact VA Environmental Agents Service (131), 810 Vermont Avenue, N.W., Washington, DC 20420, (202-565-4183).

3. Referral to a genetic disease specialist or program.

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**SAMPLE AND INSTRUCTIONS FOR COMPLETING VA FORM 10-9009c, PERSIAN GULF REGISTRY
CODE SHEET, PART III, UNIFORM CASE ASSESSMENT PROTOCOL (UCAP), PHASE II,
FOR SPOUSES AND CHILDREN OF PERSIAN GULF WAR VETERANS**

1. General Instructions for Completing VA Form 10-9009c, Part III, Phase II Persian Gulf Registry Examination.

a. The Phase II examination should be performed after the completion of the Phase I registry examination and a thorough clinically-based evaluation of the patient's symptoms as deemed necessary by the examining non-VA physician (Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.)). This protocol constitutes a set of clinical practice guidelines for the evaluation of individuals with unexplained illnesses after their service, or their spouse's and/or parent's military service, in the Persian Gulf. These guidelines should be utilized with a high degree of medical judgment dependent on numerous factors such as type and severity of complaints, general health status, age, etc. After completion of the relevant portions of the protocol, the non-VA physician (M.D. or D.O.) should complete the code sheet in the following manner:

b. VA Veterans' Registry Coordinators (VRC) will follow reporting requirements described in Chapter 2, Appendix 2D, will apply to Part III, VA Form 10-9009c.

c. Part III of the code sheet should be completed at the time of the examination by the non-VA physician. A completed Part III will be returned to VA Medical Administration Service (MAS) for completion of ICD-9-CM codes where appropriate.

2. Instructions for Completing VA Form 10-9009c, Part III (Phase II).

a. Tests and Consultations (Only those items which are related to the veterans symptoms and deemed necessary by the examining physician should be completed; leave test and consult questions that are not applicable blank.)

(1) Item 1. Were the following tests performed? Make a solid mark in one of the appropriate ovals (Items 2 through 6B) on the code sheet, using the following options:

- () = Yes
() = No

(2) Item 2. Blood Tests

- (a) Complete Blood Count (CBC)?
- (b) Skin Erythema Dose (SED) Rate?
- (c) C-Reactive Protein?
- (d) Rheumatoid Factor?
- (e) Fluorescent Anti-Nuclear Antibody (ANA)?
- (f) Glutamic Oxaloacetic Transaminase (SGOT) (AST)?
- (g) Transaminase Glutamic Pyruvate (SGPT) (ALT)?
- (h) Lactic Acid Hydrogenase (LDH)?
- (i) Alkaline Phosphatase?

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- (j) Créatine Phosphokinase (CPK)?
- (k) Hepatitis B Surface Antibody?
- (l) Hepatitis B Core Antigen?
- (m) Venereal Disease Research Laboratory (VDRL)?
- (n) Vitamin B-12?
- (o) Folate?
- (p) Human Immunodeficiency Virus (HIV)?
- (q) Thyroxine Total Serum (T4)?
- (r) Thyroid Stimulating Hormone (TSH)?
- (3) Item 3. Urinalysis?
- (4) Item 4. Tuberculosis (TB) Skin Test Purified Protein Derivative (PPD)?
- (5) Item 5. Chest X-ray?
- (6) Item 6. Psychiatry Consult?

(a) Item 6A. Structured Clinical Interview for Diagnoses (SCID) for Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised (DSM-III-R). Was the SCID interview given?

(b) Item 6B. Clinical Administered Post-Traumatic Stress Disorder (PTSD) Scale (CAPS). Was the CAPS PTSD performed?

(7) Item 7. List of Diagnoses. Based on any of the tests or consultations listed in Items 1-6B, non VA-physician (M.D. or D.O.) should provide a clear, concise narrative description of diagnoses on the code sheet. If none, leave blank. *NOTE: VA MAS coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid. When using alpha/numeric ICD-9-CM coding sections; i.e., V191, complete horizontal blocks with the alpha/numeric code, then leave the first vertical (numeric) column blank, completing the second and remaining columns by filling in appropriate ovals.*

(8) Item 8. Block 40. Psychology-Neuropsychological Test. Was this test performed? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- () = Yes
- () = No

Item 8A. List of Diagnoses. Non VA-physician should provide clear, concise narrative description of diagnoses. If none, leave blank. *NOTE: VA MAS coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.*

(9) Item 9. Infectious Disease-Screening Examination. Was this examination performed? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- () = Yes
- () = No

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Item 9A. List of Diagnoses. Non-VA physician should provide narrative description of diagnoses. If none, leave blank. **NOTE:** VA MAS coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.

(10) Item 10. Dental Examination. Was this examination performed? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- () = Yes
() = No

Item 10A. List of Diagnoses. Dentist will provide narrative description of diagnoses. If none, leave blank. **NOTE:** VA MAS coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.

SYMPTOM-SPECIFIC EXAMINATIONS, PHASE II

NOTE: Complete only those questions which are appropriate to the veteran's symptoms. Otherwise leave these blocks blank.

(11) Item 11. Diarrhea and/or Abdominal Pain

(a) Item 11A. Did patient receive a Gastrointestinal (GI) consult? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- () = Yes
() = No

(b) Item 11B. List Diagnoses. Non-VA physician should provide clear, concise narrative description of diagnoses. If none, leave blank. **NOTE:** VA MAS coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.

(12) Item 12. Headache and/or Memory Loss

(a) 12A. Did patient receive Neurology Consult? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- () = Yes
() = No

(b). Item 12B. List Diagnoses. Non-VA physician will provide clear, concise narrative description of diagnoses. If none, leave blank. **NOTE:** VA MAS coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.

(13) Item 13. Muscle Aches or Numbness

(a) Item 13A. Did patient receive a Neurology consult? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- () = Yes
() = No

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(b) Item 13B. List Diagnoses. Non-VA physician will provide clear, concise narrative description of diagnoses. If none, leave blank. **NOTE:** VA MAS coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.

(14) Item 14. Chronic Fatigue

(a) Item 14A. Did patient receive consult(s) relating to chronic fatigue? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- () = Yes
() = No

(b) Item 14B. List Diagnoses. Non-VA physician will provide clear, concise narrative description of diagnoses. If none, leave blank. **NOTE:** VA MAS coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.

(15) Item 15. Joint Pain

(a) Item 15A. Rheumatology Consult. Did patient receive Rheumatology consult? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- () = Yes
() = No

(b) Item 15B. List Diagnoses. Non-VA physician will provide clear, concise narrative description of diagnoses. If none, leave blank. **NOTE:** VA MAS coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.

(16) Item 16. Chronic Cough and/or Shortness of Breath

(a) Item 16A. Pulmonary Consult. Did patient receive Pulmonary consult? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- () = Yes
() = No

(b) Item 16B. List Diagnoses. Non-VA physician will provide clear, concise narrative description of diagnoses. If none, leave blank. **NOTE:** VA MAS coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.

(17) Item 17. Skin Rash

(a) Item 17A. Dermatology Consult. Did patient receive a dermatology consult? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- () = Yes
() = No

(b) Item 17B. List Diagnoses. Non-VA physician will provide clear, concise narrative description of diagnoses. If none, leave blank. **NOTE:** VA coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.

(18) Item 18. Vertigo and/or Tinnitus

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(a) Item 18A. Audiology Consult? Did patient receive an audiology consult? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- ☐ = Yes
☐ = No

(b) Item 18B. List Diagnoses. Non-VA physician will provide clear, concise narrative description of diagnoses. If none, leave blank. *NOTE: VA coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.*

(19) Item 19. Chest Pain and/or Palpitations

(a) Item 19A. Cardiology Consult? Did patient receive a cardiology consult? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- ☐ = Yes
☐ = No

(b) Item 19B. List Diagnoses. Non-VA physician will provide are to provide clear, concise narrative description of diagnoses. If none, leave blank. *NOTE: VA coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.*

(20) Item 20. Reproductive Concerns

(a) Item 20A. Did male patient receive a urology consult? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- ☐ = Yes
☐ = No

(b) Item 20B. Did female patient receive a gynecology consult? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- ☐ = Yes
☐ = No

(c) Item 20C. List Diagnoses. Non-VA physician will provide clear, concise narrative description of diagnoses. If none, leave blank. *NOTE: VA coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks and a solid mark in the ovals of the grid.*

(21) Item 21A-J. Final Diagnoses. Non-VA physician will provide a clear, concise narrative description of up to 10 major definite medical diagnoses on lines 20A-J, listing primary diagnosis in Item 21A. Leave blank if no diagnosis is made. *NOTE: VA coders: Enter ICD-9-CM corresponding to diagnostic narrative in the upper blocks of the grid and a solid mark in the ovals of the grid.*

(22) Item 22. After completing UCAP, Phase II, the non-VA physician feels that the veteran's spouse or child has an unexplained illness? On the code sheet, make a solid mark in one of the appropriate ovals, using one of the following options:

- ☐ = Yes
☐ = No

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SAMPLE OF COMPLETED VA FORM 10-9009c, PART III
UCAP (UNIFORM CASE ASSESSMENT PROTOCOL), PHASE II

NAME: JONES, JANICE SSN: 11-03-1111	
PHASE II (UNIFORM CASE ASSESSMENT (UCA) OF VETERAN'S SPOUSE OR CHILD)	
1. WERE THE FOLLOWING TESTS PERFORMED?	
2. BLOOD TESTS	
Y N ☐ A. CBC (Complete Blood Count) ☐ B. SED Rate (Skin Erythema Dose) ☐ C. C-Reactive Protein ☐ D. Rheumatoid Factor ☐ E. Fluorescent ANA (Anti-Nuclear Anti-Body) ☐ F. SGOT (AST) (Glutamic Oxaloacetic Transaminase) ☐ G. SGPT (ALT) (Transaminase Glutamic Pyruvate) ☐ H. LDH (Lactic Acid Hydrogenase) ☐ I. Alkaline Phosphatase ☐ J. CPK (Creatine Phosphokinase) ☐ K. Hepatitis B Surface Antibody ☐ L. Hepatitis B Core Antigen ☐ M. VDRL (Venereal Disease Research Laboratory) ☐ N. Vitamin B-12 ☐ O. Folate ☐ P. HIV (Human Immuno-Deficiency) ☐ Q. T4 (Thyroxine Total Serum) ☐ R. TSH (Thyroid Stimulating Hormone)	
3. URINALYSIS	
☐ Yes ☐ No	
4. TB SKIN TEST (PPD) (Tuberculin Skin Test Purified Protein Derivative)	
☐ Yes ☐ No	
5. CHEST XRAY	
☐ Yes ☐ No	
6. PSYCHIATRIC EVALUATION	
☐ Yes ☐ No	
6A. SCID for DSM-III-R (Structured Clinical Interview for Diagnosis)	
☐ Yes ☐ No	
6B. CAPS PTSD Scale (Clinical Administered Post Traumatic Stress Disorder)	
☐ Yes ☐ No	
7. LIST DIAGNOSES, VA MAS CODERS: ENTER ICD-9-CM CODE. IF NONE, LEAVE BLANK.	
DESCRIBE DIAGNOSES (Narrative)	
1. _____ ICD-9-CODES 2. _____ ICD-9-CODES 3. _____ ICD-9-CODES 4. _____ ICD-9-CODES 5. _____ ICD-9-CODES 6. _____ ICD-9-CODES 7. _____ ICD-9-CODES 8. _____ ICD-9-CODES 9. _____ ICD-9-CODES 10. _____ ICD-9-CODES 11. _____ ICD-9-CODES 12. _____ ICD-9-CODES 13. _____ ICD-9-CODES 14. _____ ICD-9-CODES 15. _____ ICD-9-CODES 16. _____ ICD-9-CODES 17. _____ ICD-9-CODES 18. _____ ICD-9-CODES 19. _____ ICD-9-CODES 20. _____ ICD-9-CODES	
7. (CONTINUED)	
2. _____ ICD-9-CODES	
3. _____ ICD-9-CODES	
8. PSYCHOLOGY	
NEUROPSYCHOLOGICAL TEST? ☐ Yes ☐ No	
8A. List diagnoses, VA MAS coders: Enter ICD-9-CM codes. If none, leave blank. Describe Diagnoses (Narrative)	
1. _____ ICD-9-CODES	
2. _____ ICD-9-CODES	
3. _____ ICD-9-CODES	
4. _____ ICD-9-CODES	
5. _____ ICD-9-CODES	
6. _____ ICD-9-CODES	
7. _____ ICD-9-CODES	
8. _____ ICD-9-CODES	
9. _____ ICD-9-CODES	
10. _____ ICD-9-CODES	
11. _____ ICD-9-CODES	
12. _____ ICD-9-CODES	
13. _____ ICD-9-CODES	
14. _____ ICD-9-CODES	
15. _____ ICD-9-CODES	
16. _____ ICD-9-CODES	
17. _____ ICD-9-CODES	
18. _____ ICD-9-CODES	
19. _____ ICD-9-CODES	
20. _____ ICD-9-CODES	

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NAME: JONES, JANICE SSN: 011-03-1111	
13. MUSCLE PAINS AND/OR NUMBNESS ☒ Yes ☐ No 13A. Neurology consult?	15. JOINT PAIN 15A. Rheumatology consult? ☐ Yes ☐ No
13B. List diagnoses, VA MAS codes; Enter ICD-9-CM codes. If none, leave blank. Describe Diagnoses (Narrative)	15B. List diagnoses, VA MAS codes; Enter ICD-9-CM codes. If none, leave blank. Describe Diagnoses (Narrative)
1. _____ ICD-9-CODES 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99	1. _____ ICD-9-CODES 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99
2. _____ ICD-9-CODES 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99	2. _____ ICD-9-CODES 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99
16. CHRONIC FATIGUE 16A. Chronic Fatigue? ☒ Yes ☐ No	16. CHRONIC COUGH AND/OR SHORTNESS OF BREATH 16A. Pulmonary consult? ☐ Yes ☐ No
16B. List diagnoses, VA MAS codes; Enter ICD-9-CM codes. If none, leave blank. Describe Diagnoses (Narrative)	16B. List diagnoses, VA MAS codes; Enter ICD-9-CM codes. If none, leave blank. Describe Diagnoses (Narrative)
1. APNEA SLEEP _____ ICD-9-CODES 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99	1. _____ ICD-9-CODES 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99
2. _____ ICD-9-CODES 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99	2. _____ ICD-9-CODES 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99

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NAME: <u>KNES, JANICE SSN: 11-13-111</u>	
17. SKIN RASH	
17A. Dermatology consult? ☐ Yes ☐ No	
17B. List diagnoses, VA MAS codes: Enter ICD-9-CM codes. If none, leave blank. Describe Diagnoses (Narrative)	
1.	ICD-9-CODES
2.	ICD-9-CODES
18. VERTIGO AND/OR TINNITUS	
18A. Audiology consult? ☐ Yes ☐ No	
18B. List diagnoses, VA MAS codes: Enter ICD-9-CM codes. If none, leave blank. Describe Diagnoses (Narrative)	
1.	ICD-9-CODES
2.	ICD-9-CODES
19. CHEST PAIN AND/OR PALPITATIONS	
19A. Cardiology consult? ☐ Yes ☐ No	
19B. List diagnoses, VA MAS codes: Enter ICD-9-CM codes. If none, leave blank. Describe Diagnoses (Narrative)	
1.	ICD-9-CODES
2.	ICD-9-CODES
20. REPRODUCTIVE CONCERNS	
20A. Males - Urology consult? ☐ Yes ☐ No	
20B. Females - GYN consult? ☐ Yes ☐ No	
20C. List diagnoses, VA MAS codes: Enter ICD-9-CM codes. If none, leave blank. Describe Diagnoses (Narrative)	
1.	ICD-9-CODES
2.	ICD-9-CODES

No

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SAMPLE COVER LETTER TO NON-VA PHYSICIAN

(Date)

Name/Address

Dear _____:

Some Persian Gulf War veterans have expressed concerns about health problems of their spouses and children. Although the Department of Veterans Affairs (VA) has no authority to provide registry examinations or treatment to these family members, the Secretary of the Department of Veterans Affairs, as mandated by Public Law 103-446, dated November 2, 1995, has authorized, recording medical data of veteran's family members which is submitted by Non-VA licensed physicians. This information will be entered into a Persian Gulf Veterans' Spouse and Children Registry.

We are providing you with a protocol including a set of clinical practice guidelines for the evaluation of the Persian Gulf veteran's spouse or child. These guidelines should be utilized with a high degree of medical judgment. The extent of diagnostic testing performed is dependent on numerous factors, such as type and severity of complaints, general health status, age, etc.

After completion of the portions of the enclosed protocol, which you deem clinically indicated, you should enter the relevant information onto the code sheet following the instructions in enclosed Chapter 5, Appendix 5B. We will be pleased to respond to any questions relating to these documents. Our telephone number is _____.

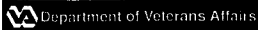
Once the code sheet is completed, this document and related medical history with progress notes should be returned to the following address to be included in the veteran's medical record and VA Persian Gulf Registry database.

Your assistance in evaluating, treating and providing the requested documentation medical data, is appreciated.

Sincerely,

 (Signature)

(Type Name and Title)



PERSIAN GULF REGISTRY CODE SHEET										TT # 1	1. Use PTF Number Only	FACILITY NO.			SUFFIX		
												(2)	(3)	(4)	(5)	(6)	(7)
PART 1 (Phase I)																	
The information the veteran supplies may be disclosed outside the VA to Federal, State and local government agencies and National Health Organizations to assist in the development of programs for research purposes and other uses as stated in the "Notice of Systems of VA Records" published in the Federal Register in accordance with the Privacy Act of 1974																	
INSTRUCTIONS: Please print. Use only one letter or number per block. If possible use black ballpoint or felt-tip pen. Shaded areas for VA use only. (DO NOT USE BLUE INK)																	
2. LAST NAME (8-33)																	
3. FIRST NAME (34-48)																	
4. MIDDLE NAME (49-55)																	
5. SOCIAL SECURITY NUMBER (60-68)																	
7. D.O.B. (Complete all blanks)																	
MO (70-71) DAY (72-73) YR (74-75)																	
8. ADDRESS (Street Name and Apartment Number, if applicable) 76-101																	
9A. CITY OR TOWN (102-127)																	
9B. COUNTY																	
STATE																	
9C. ZIP CODE (128-132)																	
9D. LEAVE BLANK (133) (134) (135) (136)																	
9E. COUNTY (137-139) STATE (140-141)																	
9. RACE/ETHNICITY (Enter one code at right)																	
1=American Indian or Alaskan Native 3=Black, Not of Hispanic Origin 5=Hispanic 142																	
2=Asian or Pacific Islander 4=White, Not of Hispanic Origin 6=Unknown																	
10. MARITAL STATUS (Enter one code at right)																	
1=Married 3=Separated 5=Single, Never Married 143																	
2=Divorced 4=Widowed																	
11. SEX (Enter one code at right) 144																	
Male-Male Female-Female																	
12. CURRENT STATUS (Enter one code at right)																	
1=Inpatient 3=Incarcerated 5=Active Duty Inpatient 145																	
2=Outpatient 4=Active Duty (Outpatient)																	
13. BRANCH OF SERVICE (If more than one, enter latest Persian Gulf Service)																	
1=Army 3=Navy 5=Coast Guard 146																	
2=Air Force 4=Marine Corps 6=Other																	
14. DID VETERAN HAVE MILITARY SERVICE IN PERSIAN GULF AREA?																	
Y=Yes (If "Yes", list below the dates of veteran's last two periods of service there) N=No (If "No", Persian Gulf Veterans not eligible for PGR exam.) 147																	
A. LAST PERIOD																	
F R O M MO (148-149) YR (150-151) T O MO (152-153) YR (154-155)																	
B. NEXT TO LAST PERIOD																	
F R O M MO (156-157) YR (158-159) T O MO (160-161) YR (162-163)																	
15A. IN WHAT AREAS DID VETERAN SERVE?																	
(Enter appropriate code in block 164)																	
1=Combat Zone 164																	
2=Other Land Area																	
3=Sea Duty																	
15B. IF OTHER SERVICE OR "DON'T KNOW"																	
(Enter appropriate code in block 164)																	
4=Other (Specify i.e. Air Force, Ground or Air Crew, etc.)																	
5=Don't Know																	
16. MILITARY UNITS AND MOS																	
16A. LIST MILITARY UNITS IN WHICH VETERAN SERVED.																	
PLEASE SPECIFY COMPLETE UNABBREVIATED TITLE. (Company, battalion, etc.)																	
16B. LIST MILITARY OCCUPATIONAL SPECIALTY (MOS)																	
16C. WERE ACTUAL DUTIES DIFFERENT FROM MOS?																	
ENTER EITHER OF THE FOLLOWING CODES IN BLOCK 166																	
Y = Yes N = No 166																	
16D. IF YES, LIST HERE AND IN CONSOLIDATED HEALTH RECORD																	
16E. ENTER THE NAME OF THE UNIT IN WHICH VETERAN HAD THE LONGEST AND NEXT TO LONGEST PERIOD OF SERVICE WHILE IN THE PERSIAN GULF																	
NOTE A&B: Those units could be different from the one to which the veterans was assigned if veterans was on detached duty.																	
17. ENTER THE DATES OF THE LAST TWO PERIODS OF SERVICE (If different from above)																	
A. LAST PERIOD																	
F R O M MO (167-168) YR (169-170) T O MO (171-172) YR (173-174)																	
B. NEXT TO LAST PERIOD																	
F R O M MO (175-176) YR (177-178) T O MO (179-180) YR (181-182)																	

NAME: _____
SSN: _____

18. VETERANS EXPOSURE TO ENVIRONMENTAL FACTORS (ENTER APPROPRIATE CODES)		
18A. ARE YOU CURRENTLY SMOKING CIGARETTES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 183. IF NO, GO TO ITEM 18D.	Y=YES N=NO	(183)
18B. IF YES, HOW MANY YEARS HAVE YOU BEEN SMOKING CIGARETTES? ENTER THE NUMBER OF YEARS IN BLOCK 184 AND 185.		(184) (185)
18C. ON THE AVERAGE HOW MANY PACKS ARE YOU SMOKING PER DAY? ENTER THE NUMBER OF PACKS IN BLOCKS 186 AND 187		(186) (187)
18D. HAVE YOU SMOKED CIGARETTES IN THE PAST? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 188. IF NO, GO TO ITEM 18G.	Y=YES N=NO	(188)
18E. IF YES, HOW MANY YEARS HAD YOU SMOKED? ENTER NUMBER OF YEARS IN BLOCKS 189 AND 190.		(189) (190)
18F. ON THE AVERAGE, HOW MANY PACKS DID YOU SMOKE PER DAY? ENTER THE NUMBER OF PACKS IN BLOCKS 191 AND 192.		(191) (192)
18G-Z1. WHILE IN THE PERSIAN GULF DO YOU BELIEVE YOU WERE EXPOSED TO ANY OF THE FOLLOWING:		
18G. SMOKE FROM OIL FIRES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 193.	Y=YES N=NO U=UNKNOWN	(193)
18H. SMOKE OR FUMES FROM TENT HEATERS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 194.	Y=YES N=NO U=UNKNOWN	(194)
18I. CIGARETTE SMOKE (PASSIVE) FROM OTHERS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 195.	Y=YES N=NO U=UNKNOWN	(195)
18J. DIESEL AND/OR OTHER PETROCHEMICAL FUMES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 196.	Y=YES N=NO U=UNKNOWN	(196)
18K. EXPOSURE TO BURNING TRASH/FECES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 197.	Y=YES N=NO U=UNKNOWN	(197)
18L. SKIN EXPOSURE TO DIESEL OR OTHER PETROCHEMICAL FUEL? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 198.	Y=YES N=NO U=UNKNOWN	(198)
18M. CARC (CHEMICAL AGENT RESISTANT COMPOUND)? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 199.	Y=YES N=NO U=UNKNOWN	(199)
18N. OTHER PAINTS AND/OR SOLVENTS AND/OR PETROCHEMICAL SUBSTANCES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 200.	Y=YES N=NO U=UNKNOWN	(200)
18O. DEPLETED URANIUM? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 201.	Y=YES N=NO U=UNKNOWN	(201)
18P. MICROWAVES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 202.	Y=YES N=NO U=UNKNOWN	(202)
18Q. PERSONAL PESTICIDE USE, INCLUDING CREAMS, SPRAYS OR FLEA COLLARS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 203.	Y=YES N=NO U=UNKNOWN	(203)
18R. NERVE GAS OR OTHER NERVE AGENTS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 204.	Y=YES N=NO U=UNKNOWN	(204)
18S. DRUG (PYRIDOSTIGMINE) USED TO PROTECT AGAINST NERVE AGENTS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 205.	Y=YES N=NO U=UNKNOWN	(205)
18T. MUSTARD GAS OR OTHER AGENTS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 206.	Y=YES N=NO U=UNKNOWN	(206)
18U. ATE OR DRANK FOOD CONTAMINATED WITH SMOKE, OIL OR OTHER CHEMICAL? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 207.	Y=YES N=NO U=UNKNOWN	(207)

NAME: _____

SSN: _____

18V. ATE FOOD OTHER THAN PROVIDED BY ARMED FORCES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 208.	Y=YES N=NO U=UNKNOWN	(208)
18W. BATHED IN OR DRANK WATER CONTAMINATED WITH SMOKE OR OTHER CHEMICAL? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 209.	Y=YES N=NO U=UNKNOWN	(209)
18X. BATHED IN WATER OTHER THAN PROVIDED BY ARMED FORCES? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 210.	Y=YES N=NO U=UNKNOWN	(210)
18Y. IMMUNIZATION AGAINST ANTHRAX? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 211.	Y=YES N=NO U=UNKNOWN	(211)
18Z. IMMUNIZATION AGAINST BOTULISM? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 212.	Y=YES N=NO U=UNKNOWN	(212)

18Z1. OTHER EXPOSURES? ENTER HERE AND IN CHR ONLY.

19. DID VETERAN HAVE ANY OF THE FOLLOWING EXPERIENCES WHILE IN THE PERSIAN GULF? ENTER APPROPRIATE CODE.

19A. DID YOU EVER GO ON COMBAT PATROLS OR HAVE OTHER VERY DANGEROUS DUTY? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 213. 1=NO 2=1-3X 3=4-12X 4=13-50X 5=51+ TIMES	(213)

19B. WERE YOU EVER UNDER ENEMY FIRE (INCLUDING "SCUDS")? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 214. 1=NEVER 2=1DAY 3=<1 WEEK 4=1-4 WEEKS 5=4 WEEKS OR MORE	(214)

19C. WHAT PERCENTAGE OF PEOPLE IN YOUR UNIT WERE KILLED (KIA), WOUNDED OR MISSING IN ACTION (MIA), ENTER ONE OF THE FOLLOWING CODES IN BLOCK 215. 1=NONE 2=1-25% 3=26-50% 4=51-75% 5=76% OR MORE	(215)

19D. HOW OFTEN DID YOU SEE SOMEONE HIT BY INCOMING OR OUTGOING ROUNDS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 216. 1=NEVER 2=1-2X 3=3-12X 4=13-50X 5=51 OR MORE TIMES	(216)

19E. HOW OFTEN WERE YOU IN DANGER OF BEING INJURED OR KILLED (I.E. PINNED DOWN, OVERRUN, AMBUSHED, NEAR MISS, ETC.)? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 217. 1=NEVER 2=1-2X 3=3-12X 4=13-50X 5=51 OR MORE TIMES	(217)

19F. DID YOU WITNESS CHEMICAL ALARMS? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 218.	Y=YES N=NO U=UNKNOWN	(218)

20. VETERAN'S HEALTH (VETERAN'S EVALUATION)

20A. WHICH BEST DESCRIBES VETERAN'S HEALTH AFTER PERSIAN GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 219. 1=Very Good 2=Good 3=Fair 4=Poor 5=Very Poor	(219)

21. VETERAN'S FUNCTIONAL IMPAIRMENT

21A. WHICH BEST DESCRIBES VETERAN'S OWN ASSESSMENT OF FUNCTIONAL IMPAIRMENT? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 220. 1=NO IMPAIRMENT 2=SLIGHT IMPAIRMENT 3=MODERATE IMPAIRMENT 4=SEVERE IMPAIRMENT	(220)

21B. HOW MANY WORKDAYS WERE LOST BY VETERAN DUE TO ILLNESS IN THE PAST 90 DAYS? ENTER NUMBER OF DAYS LOST IN BLOCKS 221-222.	(221)	(222)

22. EVIDENCE OF BIRTH DEFECTS AND INFANT DEATH(S) AMONG VETERAN'S CHILDREN AND PROBLEMS WITH PREGNANCY AND INFERTILITY.

22A. HOW MANY CHILDREN DOES VETERAN HAVE? ENTER NUMBER IN BLOCKS 223 AND 224. (I.E. 05). IF NONE, LEAVE BLANK AND GO TO ITEM 22C.	(223)	(224)

NAME: _____

SSN: _____

22B. HOW MANY OF THESE CHILDREN WERE BORN WITH BIRTH DEFECTS? (BIRTH DEFECTS ARE ANY STRUCTURAL, FUNCTIONAL, OR BIOCHEMICAL ABNORMALITY AT BIRTH WHETHER GENETICALLY DETERMINED OR INDUCED DURING GESTATION THAT IS NOT DUE TO INJURIES SUFFERED DURING BIRTH.) ENTER NUMBER IN BLOCKS 225 AND 226. IF NONE, GO TO ITEM 22C.	(225)	(226)
22B1. HOW MANY OF THESE CHILDREN WERE CONCEIVED BEFORE GULF SERVICE? ENTER THE NUMBER OF CHILDREN IN BLOCKS 227 AND 228. IF NONE, LEAVE BLANK AND GO TO ITEM 22B2.	(227)	(228)
22B1(a) STATE MATERNAL AGE AT CONCEPTION OF FIRST CHILD CONCEIVED BEFORE GULF SERVICE? ENTER AGE IN BLOCKS 229 AND 230.	(229)	(230)
22B2. HOW MANY OF THESE CHILDREN WERE CONCEIVED DURING AND AFTER GULF SERVICE? ENTER NUMBER IN BLOCK 231 AND 232. IF NONE, LEAVE BLANK AND GO TO ITEM 22C.	(231)	(232)
22B2(a) STATE MATERNAL AGE AT CONCEPTION OF FIRST CHILD CONCEIVED DURING AND AFTER GULF SERVICE? ENTER AGE IN BLOCKS 229 AND 230.	(233)	(234)
22C. HAS VETERAN OR SPOUSE HAD INFERTILITY PROBLEMS? (INFERTILITY PROBLEMS OF VETERAN OR SPOUSE BECOMING PREGNANT. NOTE: INFERTILITY - RELATIVE STERILITY DEFINED AS INABILITY TO CONCEIVE AFTER 12 OR MORE MONTHS OF INTERCOURSE WITHOUT USE OF CONTRACEPTION AND WHEN NEITHER SPOUSE IS SURGICALLY STERILIZED.) ENTER ONE OF THE FOLLOWING CODES IN BLOCK 235. IF NO, GO TO ITEM 22D.	(235)	
Y=YES N=NO		
22C1. HAS VETERAN OR SPOUSE HAD INFERTILITY BEFORE GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 236. IF NO, GO TO ITEM 22C2.	(236)	
Y=YES N=NO		
22C1(a) STATE MATERNAL AGE DURING FIRST ATTEMPTS TO CONCEIVE. ENTER AGE IN BLOCKS 237 AND 238.	(237)	(238)
22C2. HAS VETERAN OR SPOUSE HAD INFERTILITY AFTER RETURN FROM GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 239. IF NO, GO TO ITEM 22D.	(239)	
Y=YES N=NO		
22C2(a) STATE MATERNAL AGE DURING FIRST ATTEMPTS TO CONCEIVE. ENTER AGE IN BLOCKS 240 AND 241.	(240)	(241)
22D. HAS VETERAN OR SPOUSE HAD MISCARRIAGE(S) (NOTE: MISCARRIAGES ARE SPONTANEOUS EXPULSION OF THE PRODUCTS OF CONCEPTION BEFORE 20 WEEKS OF GESTATION - SPONTANEOUS ABORTION) ENTER ONE OF THE FOLLOWING CODES IN BLOCK 242. IF NO, GO TO ITEM 22E.	(242)	
Y=YES N=NO		
22D1. HAS VETERAN OR SPOUSE HAD MISCARRIAGES BEFORE PERSIAN GULF? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 243. IF NO, GO TO ITEM 22D2.	(243)	
Y=YES N=NO		
22D1(a) STATE MATERNAL AGE AT CONCEPTION. ENTER AGE IN BLOCKS 244 AND 245.	(244)	(245)
22D2. HAS VETERAN OR SPOUSE HAD MISCARRIAGES AFTER PERSIAN GULF? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 246. IF NO, GO TO ITEM 22E.	(246)	
Y=YES N=NO		
22D2(a) STATE MATERNAL AGE AT CONCEPTION. ENTER AGE IN BLOCKS 247 AND 248.	(247)	(248)
22E. HAS VETERAN OR SPOUSE HAD STILL BIRTH(S)? (NOTE: STILL BIRTH IS BIRTH AFTER 20 WEEKS OF GESTATION OF AN INFANT WHO SHOWED NO EVIDENCE OF LIFE AFTER BIRTH.) ENTER ONE OF THE FOLLOWING CODES IN BLOCK 249. IF NO, GO TO ITEM 22F.	(249)	
Y=YES N=NO		
22E1. HAS VETERAN OR SPOUSE HAD STILL BIRTH(S) BEFORE GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 250. IF NO, GO TO ITEM 22E2.	(250)	
Y=YES N=NO		
22E1(a) STATE MATERNAL AGE AT CONCEPTION. ENTER AGE IN BLOCKS 251 AND 252.	(251)	(252)
22E2. HAS VETERAN OR SPOUSE HAD STILL BIRTH(S) AFTER RETURN FROM GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 253. IF NO, GO TO ITEM 22F.	(253)	
Y=YES N=NO		
22E2(a) STATE MATERNAL AGE AT CONCEPTION. ENTER AGE IN BLOCKS 254 AND 255.	(254)	(255)
22F. HAS VETERAN OR SPOUSE HAD INFANT DEATH(S). (NOTE: DEATH THAT OCCURRED WITHIN ONE YEAR OF BIRTH AMONG BABIES BORN ALIVE.) ENTER ONE OF THE FOLLOWING CODES IN BLOCK 256. IF NO, GO TO ITEM 22G.	(256)	
Y=YES N=NO		
22F1. HAS VETERAN OR SPOUSE HAD INFANT DEATH(S) BEFORE GULF SERVICE? ENTER ONE OF THE FOLLOWING CODES IN BLOCK 257. IF NO, GO TO ITEM 22F2.	(257)	
Y=YES N=NO		
22F1(a) STATE MATERNAL AGE AT CONCEPTION. ENTER AGE IN BLOCKS 258 AND 259.	(258)	(259)
22F2. HAS VETERAN OR SPOUSE HAD INFANT DEATH(S) AFTER GULF SERVICE ENTER ONE OF THE FOLLOWING CODES IN BLOCK 260. IF NO, GO TO ITEM 22G.	(260)	
Y=YES N=NO		

NAME: _____

SSN: _____

22F2(A) STATE MATERNAL AGE AT CONCEPTION. ENTER AGE IN BLOCKS 261 AND 262.										(261-262)																
22G IF A WOMAN VETERAN REPORTS SHE WAS PREGNANT IN PERSIAN GULF, RECORD DATE OF CHILD'S BIRTH AND HOSPITAL OF BIRTH HERE AND IN VETERAN'S CHR ONLY TO FACILITATE FOLLOW-UP, IF NEEDED. (AAC WILL NOT ENTER THIS DATA IN PGR DATABASE).																										
DATE OF BIRTH						MONTH / DAY / YEAR																				
NAME OF HOSPITAL						_____																				
LOCATION						_____																				
PART II TO BE COMPLETED BY EXAMINING PHYSICIAN																										
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="3">23. DATE OF EXAM</th> </tr> <tr> <td style="text-align: center;">MONTH (263-264)</td> <td style="text-align: center;">DAY (265-266)</td> <td style="text-align: center;">YEAR (267-270)</td> </tr> <tr> <td style="height: 20px;"></td> <td></td> <td></td> </tr> </table>								23. DATE OF EXAM			MONTH (263-264)	DAY (265-266)	YEAR (267-270)				<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>24. TOTAL NO. OF VETERAN'S COMPLAINTS.</td> <td colspan="2" style="text-align: center;">(271-272)</td> </tr> <tr> <td style="height: 20px;"></td> <td></td> <td></td> </tr> </table>				24. TOTAL NO. OF VETERAN'S COMPLAINTS.	(271-272)				
23. DATE OF EXAM																										
MONTH (263-264)	DAY (265-266)	YEAR (267-270)																								
24. TOTAL NO. OF VETERAN'S COMPLAINTS.	(271-272)																									
25A/J. LIST UP TO TEN MAJOR, CURRENT SYMPTOMS, ICD 9 CODES, MO. & YR OF ONSET. DURATION IN MOS AND IF SYMPTOM IS CURRENTLY PRESENT ON LINES A-J, ITEMS 1-5. IF VETERAN HAS MORE THAN 10, ENTER THE MOST SEVERE & ADDITIONAL SYMPTOMS IN CHR. MAS CODERS: USE ITEM 2, BLOCKS 271-320 FOR ICD-9-CM CODES.																										
(1) DESCRIBE SYMPTOM NARRATIVE	(2) ICD-9-CODES (273-322)				(3) MO. & YR OF ONSET MONTH YEAR (323-382)				(4) DURATION (MONTHS) (383-402)		(5) CURRENTLY PRESENT? Y=Yes N=NO (403-412)															
A	(273-277)					(323-328)					(383-384)				(403)											
B	(278-282)					(329-334)					(385-386)				(404)											
C	(283-287)					(335-340)					(387-388)				(405)											
D	(288-292)					(341-346)					(389-390)				(406)											
E	(293-297)					(347-352)					(391-392)				(407)											
F	(298-302)					(353-358)					(393-394)				(408)											
G	(303-307)					(359-364)					(395-396)				(409)											
H	(308-312)					(365-370)					(397-398)				(410)											
I	(313-317)					(371-376)					(399-400)				(411)											
J	(318-322)					(377-382)					(401-402)				(412)											
25K. LIST MOST SEVERE SYMPTOM. (A SYMPTOM FROM ITEM A-J, WHICH VETERAN CONSIDERS THE MOST SEVERE I.E. CHIEF COMPLAINT). ENTER ICD-9-CM CODE IN BLOCKS.										(413-417)																
26. DIAGNOSTIC CONSULTATION. ENTER THE FOLLOWING CODES IN BLOCKS 418-435.																										
1=NO WORKUP. NO CONSULTATION DONE. 3=WORKUP/CONSULTATION DONE. DIAGNOSIS ESTABLISHED.																										
2=WORKUP/CONSULTATION DONE. UNEXPLAINED ILLNESS 4=WORKUP/CONSULTATION DONE. NO DIAGNOSIS.																										
A. ALLERGY/IMMUNOLOGY. BLOCK 418										(418)																
B. AUDIOLOGY. BLOCK 419										(419)																
C. CARDIOLOGY. BLOCK 420										(420)																
D. DENTISTRY. BLOCK 421										(421)																
E. DERMATOLOGY. BLOCK 422										(422)																
F. EAR, NOSE AND THROAT 423										(423)																
G. ENDOCRINOLOGY. BLOCK 424										(424)																
H. GASTROENTEROLOGY. BLOCK 425										(425)																

NAME: _____
 SSN: _____

I. HEMATOLOGY/ONCOLOGY. BLOCK 426	(426)
J. INFECTIOUS DISEASES/PARASITOLOGY. BLOCK 427	(427)
K. NEPHROLOGY. BLOCK 428	(428)
L. NEUROLOGY. BLOCK 429	(429)
M. OCCUPATIONAL MEDICINE. BLOCK 430	(430)
N. PULMONARY. BLOCK 431	(431)
O. PSYCHIATRY. BLOCK 432	(432)
P. PSYCHOLOGY/PSYCHOMETRIC TESTING. BLOCK 433	(433)
Q. RHEUMATOLOGY. BLOCK 434	(434)
R. OTHER, ENTER FOLLOWING CODES IN BLOCK 435	
Y=YES	(435)
N=NO	
S. ADDITIONAL WORKUPS/CONSULTATIONS PERFORMED WHICH WERE NOT LISTED IN ITEMS 26A-Q. LIST HERE AND IN CHR.	

NAME: _____

SSN: _____

27. DIAGNOSIS LIST UP TO 10 MAJOR DEFINITE MEDICAL DIAGNOSES ON LINES 27A-J. LIST PRIMARY DIAGNOSIS ON LINE A. BLOCKS 436-485 FOR CORRESPONDENCE ICD-9-CM CODES. LEAVE BLANK IF NO DIAGNOSIS IS MADE. MAS CODERS: USE ICD-9-CM CODES IN FIRST FIVE NUMBERED BLOCKS OF EACH DIAGNOSIS									
27A. DESCRIBE DIAGNOSIS (Narrative)								(27B)	
A. (PRIMARY)								ICD-9-CM (Codes)	
								(436) (437) (438) (439) (440)	
								(441) (442) (443) (444) (445)	
B.								(446) (447) (448) (449) (450)	
C.								(451) (452) (453) (454) (455)	
D.								(456) (457) (458) (459) (460)	
E.								(461) (462) (463) (464) (465)	
F.								(466) (467) (468) (469) (470)	
G.								(471) (472) (473) (474) (475)	
H.								(476) (477) (478) (479) (480)	
I.								(481) (482) (483) (484) (485)	
J.								(486) (487) (488) (489) (490)	
NOTE: CODERS: DO NOT REPEAT OR LIST SYMPTOM CODE ALREADY LISTED UNDER ITEM 25A-J.									
28. BLOCK 486 IF NO DIAGNOSIS IS MADE, ENTER "1" IN BLOCK AT RIGHT, OTHERWISE, LEAVE BLANK. THIS ITEM MUST BE CONSIDERED IN CONJUNCTION WITH ITEM 27 "DIAGNOSIS."									486
29. DISPOSITION (Enter code Y-Yes or N-No)									
29A. EXAMINATION COMPLETED?		487	29B. HOSPITALIZED AT VAMC FOR FURTHER TESTS?		488	29C. HOSPITALIZED AT VAMC FOR TREATMENT?		489	
Y=Yes	N=No		Y=Yes	N=No		Y=Yes	N=No		
29D. REFERRED FOR OUTPATIENT CARE?		490	29E. REFERRED TO PRIVATE PHYSICIAN, NON-VA CLINIC OR NON-VA HOSPITAL?		491	29F. BIOPSY?		492	
Y=Yes	N=No		Y=Yes	N=No		Y=Yes	N=No		
30. AFTER COMPLETION OF PHASE I EXAM (REFER TO PAR 6), THE PHYSICIAN HAS DETERMINED THE VETERAN HAS UNEXPLAINED ILLNESS?			493	31. HAS PHASE II EXAM (REFER TO CH. 3) BEEN INITIATED?			494		
Y=Yes	N=No			Y=Yes	N=No				
32. UTILIZE THIS SECTION FOR ADDITIONAL INFORMATION (E.G. PAR 1.07 - M-10, PT III).									
33. NAME OF EXAMINER. (PRINT FULL NAME)									
34. TITLE OF EXAMINER. (FULL TITLE OF EXAMINER)									
35. SIGNATURE OF EXAMINER.					35A. SIGNATURE OF VPR (VETERANS REGISTRY PHYSICIAN)				

NAME: _____

SSN: _____

PART III				
PHASE II - UNIFORM CASE ASSESSMENT (UCA)				
1. WERE THE FOLLOWING TESTS PERFORMED? Enter the following codes in blocks 1-24. Y = YES N = NO				
2. BLOOD TESTS, BLOCKS 1-18; OTHER - BLOCKS 19-24.				
A. CBC (COMPLETE BLOOD COUNT)	(1)	B. SED RATE? (SKIN ERETHYMA DOSE)	(2)	C. C-REACTIVE PROTEIN
	(3)		(4)	
D. RHEMATOID FACTOR?	(5)	E. FLUORESCENT ANA? (ANTI-NUCLEAR ANTI-BODY)	(6)	F. SGOT (AST)? (GLUTAMIC OXALACETIC TRANSAMINASE)
	(7)		(8)	
G. SGPT (ALT) (TRANSMINASE GLUTAMIC PYRUVATE)	(9)	H. LDH (LACTIC ACID HYDROGENASE)	(10)	I. ALKALINE PHOSPHATASE
	(11)		(12)	
J. CPK? CREATINE PHOSPHOKINASE	(13)	K. HEPATITIS B SURFACE ANTIBODY?	(14)	L. HEPATITIS B CORE ANTIGEN?
	(15)		(16)	
M. VDRL? (VENEREAL DISEASE RESEARCH LABORATORY)	(17)	N. VITAMIN B-12	(18)	O. FOLATE?
	(19)		(20)	
P. HIV (HUMAN IMMUNO- DEFICIENCY)	(21)	Q. T4 (THYROXINE TOTAL SERUM)?	(22)	R. TSH (THYROID STIMULATING HORMONE)?
	(23)		(24)	
3. URINALYSIS	(25)	4. TB SKIN TEST (PPD)? (TUBERCULOSIS SKIN TEST PURIFIED PROTEIN DERIVATIVE)	(26)	5. CHEST XRAY
	(27)		(28)	
6. PSYCHIATRIC EVALUATION?	(29)	6A. SCID FOR DSM-5-R (STRUCTURED CLINICAL INTERVIEW FOR DIAGNOSIS)	(30)	6B. CAPS PTSD SCALE (CLINICAL ADMINISTERED POST TRAUMATIC STRESS DISORDER)
	(31)		(32)	
7. LIST DIAGNOSES: MAS CODERS: ENTER ICD-9-CM CODE IN BLOCKS 25-39. IF NONE, LEAVE BLANK.				
DESCRIBE DIAGNOSES (Narrative)		ICD-9-CODES		
1.		(25)	(26)	(27)
		(28)	(29)	(30)
2.		(31)	(32)	(33)
		(34)	(35)	(36)
3.		(37)	(38)	(39)
		(40)	(41)	(42)
		(43)	(44)	(45)
8. PSYCHOLOGY-NEUROPSYCHOLOGICAL TEST? (Enter code in block 40)				
Y=Yes N=No	(40)	8A. LIST DIAGNOSES: MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 41-55. IF NONE, LEAVE BLANK.		
DESCRIBE DIAGNOSES (Narrative)		ICD-9-CODES		
1.		(41)	(42)	(43)
		(44)	(45)	(46)
2.		(47)	(48)	(49)
		(50)	(51)	(52)
3.		(53)	(54)	(55)
		(56)	(57)	(58)
		(59)	(60)	(61)
9. INFECTIOUS DISEASE - SCREENING EXAM? (Enter code in block 56)				
Y=Yes N=No	(56)	9A. LIST DIAGNOSES: MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 67-68. IF NONE, LEAVE BLANK.		
DESCRIBE DIAGNOSES (Narrative)		ICD-9-CODES		
1.		(67)	(68)	(69)
		(70)	(71)	(72)
2.		(73)	(74)	(75)
		(76)	(77)	(78)
10. DENTAL EXAM? (Enter code in block 87)				
Y=Yes N=No	(87)	10A. LIST DIAGNOSES: MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 88-99. IF NONE, LEAVE BLANK.		
DESCRIBE DIAGNOSES (Narrative)		ICD-9-CODES		
1.		(88)	(89)	(90)
		(91)	(92)	(93)
2.		(94)	(95)	(96)
		(97)	(98)	(99)

SSN: _____

11. DIARRHEA AND/OR ABDOMINAL PAIN		
11A. GI (GASTROINTESTINAL) CONSULT? (Enter code in block 78) Y = Yes N = No	78	11B. LIST DIAGNOSES. MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 79-98. IF NONE, LEAVE BLANK. DESCRIBE DIAGNOSES (Narrative)
		ICD-9-CODES (79) (80) (81) (82) (83) (84) (85) (86) (87) (88) (89) (90) (91) (92) (93) (94) (95) (96) (97) (98)
12. HEADACHE AND/OR MEMORY LOSS		
12A. NEUROLOGY CONSULT? (Enter code in block 99) Y = Yes N = No	99	12B. LIST DIAGNOSES. MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 100-109. IF NONE, LEAVE BLANK. DESCRIBE DIAGNOSES (Narrative)
		ICD-9-CODES (100) (101) (102) (103) (104) (105) (106) (107) (108) (109)
13. MUSCLE ACHES AND/OR NUMBNESS		
13A. NEUROLOGY CONSULT? (Enter code in block 110) Y = Yes N = No	110	13B. LIST DIAGNOSES. MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 111-120. IF NONE, LEAVE BLANK. DESCRIBE DIAGNOSES (Narrative)
		ICD-9-CODES (111) (112) (113) (114) (115) (116) (117) (118) (119) (120)
14. CHRONIC FATIGUE		
14A. CHRONIC FATIGUE? (Enter code in block 121) Y = Yes N = No	121	14B. LIST DIAGNOSES. MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 122-131. IF NONE, LEAVE BLANK. DESCRIBE DIAGNOSES (Narrative)
		ICD-9-CODES (122) (123) (124) (125) (126) (127) (128) (129) (130) (131)
15. JOINT PAIN		
15A. RHEUMATOLOGY CONSULT? (Enter code in block 132) Y = Yes N = No	132	15B. LIST DIAGNOSES. MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 133-142. IF NONE, LEAVE BLANK. DESCRIBE DIAGNOSES (Narrative)
		ICD-9-CODES (133) (134) (135) (136) (137) (138) (139) (140) (141) (142)
16. CHRONIC COUGH AND/OR SHORTNESS OF BREATH		
16A. PULMONARY CONSULT? (Enter code in block 143) Y = Yes N = No	143	16B. LIST DIAGNOSES. MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 144-153. IF NONE, LEAVE BLANK. DESCRIBE DIAGNOSES (Narrative)
		ICD-9-CODES (144) (145) (146) (147) (148) (149) (150) (151) (152) (153)
17. SKIN RASH		
17A. DERMATOLOGY CONSULT? (Enter code in block 154) Y = Yes N = No	154	17B. LIST DIAGNOSES. MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 155-164. IF NONE, LEAVE BLANK. DESCRIBE DIAGNOSES (Narrative)
		ICD-9-CODES (155) (156) (157) (158) (159) (160) (161) (162) (163) (164)
18. VERTIGO AND/OR TINNITUS		
18A. AUDIOLOGY? (Enter code in block 165) Y = Yes N = No	165	18B. LIST DIAGNOSES. MAS CODERS: ENTER ICD-9-CM CODES IN BLOCKS 166-175. IF NONE, LEAVE BLANK. DESCRIBE DIAGNOSES (Narrative)
		ICD-9-CODES (166) (167) (168) (169) (170) (171) (172) (173) (174) (175)

NAME: _____

SSN: _____

19. CHEST PAIN AND/OR PALPITATIONS					
19A. CARDIOLOGY CONSULT (Enter code in block 176) Y=YES N=NO	176	19B. LIST DIAGNOSES. MAS CODERS ENTER ICD-9-CM CODES IN BLOCKS 177-186. IF NONE, LEAVE BLANK.			
		DESCRIBE DIAGNOSES (Narrative)		ICD-9-CODES	
		1.	(177)	(178)	(179) (180) (181)
		2.	(182)	(183)	(184) (185) (186)
20. REPRODUCTIVE CONCERNS					
20A. MALES - UROLOGY CONSULT (Enter code in block 187) Y=YES N=NO	187	20B. LIST DIAGNOSES. MAS CODERS ENTER ICD-9-CM CODES IN BLOCKS 189-198. IF NONE, LEAVE BLANK.			
		DESCRIBE DIAGNOSES (Narrative)		ICD-9-CODES	
		1.	(189)	(190)	(191) (192) (193)
20B. FEMALES - GYN CONSULT (Enter code in block 188) Y=YES N=NO	188	2.		(194)	(195) (196) (197) (198)
21. FINAL DIAGNOSES: PHASE II					
21A. DIAGNOSES. LIST UP TO 10 MAJOR DEFINITE MEDICAL DIAGNOSES ON LINES 20A-J. LIST PRIMARY DIAGNOSIS ON LINE A. BLOCKS 199-248 OR CORRESPONDING ICD-9-CM CODES. LEAVE BLANK IF NO DIAGNOSIS IS MADE. MAS CODERS: USE ICD-9-CM CODES IN FIRST FIVE NUMBERED BLOCKS OF EACH DIAGNOSIS					
DESCRIBE DIAGNOSES (Narrative)			ICD-9-CODES		
A. (PRIMARY)			(199)	(200)	(201) (202) (203)
B.			(204)	(205)	(206) (207) (208)
C.			(209)	(210)	(211) (212) (213)
D.			(214)	(215)	(216) (217) (218)
E.			(219)	(220)	(221) (222) (223)
F.			(224)	(225)	(226) (227) (228)
G.			(229)	(230)	(231) (232) (233)
H.			(234)	(235)	(236) (237) (238)
I.			(239)	(240)	(241) (242) (243)
J.			(244)	(245)	(246) (247) (248)
					(249)
22. AFTER COMPLETING PHASE II, UNIFORM CASE ASSESSMENT PROTOCOL, THE PHYSICIAN FEELS THAT THE VETERAN HAS AN UNEXPLAINED ILLNESS? (Enter code in block 249) Y=YES N=NO					

Department of Veterans Affairs
 Veterans Health Administration
 Washington, DC 20420

VHA DIRECTIVE 96-073

December 2, 1996

**REVISIONS IN AUTHORITIES FOR PROVISION OF PRIORITY HEALTH CARE
 FOR CERTAIN VETERANS EXPOSED TO SPECIFIED TOXIC SUBSTANCES**

1. **PURPOSE:** The purpose of this Veterans Health Administration (VHA) Directive is to provide information for implementing section 102 of Public Law (Pub. L.) 104-262, the Veterans' Health Care Eligibility Reform Act of 1996.

2. POLICY

a. In general, section 102 of Pub. L. 104-262 provides that the Department of Veterans Affairs (VA) shall furnish hospital care and medical services, and may furnish nursing home care to veterans exposed to herbicides in Vietnam (Agent Orange), ionizing radiation, or a toxic substance or environmental hazard pursuant to Title 38 United States Code (U.C.S.) 1710(a)(2)(F). Any veteran already receiving hospital care, outpatient medical services, or nursing home care under VA's former priority health care authorities who would not be eligible for care under section 102 remains eligible for such care on the basis of presumed exposure with respect to the disability for which care and services were being furnished.

b. VA's amended priority health care authority with respect to each of these following three groups is discussed in greater specificity.

(1) Agent Orange Exposed Veterans

(a) Veterans who may have been exposed to herbicides in Vietnam, commonly referred to as "Agent Orange-exposed" veterans, have mandatory eligibility for hospital care, medical services, and discretionary eligibility for nursing home care for any disability, notwithstanding that there is insufficient medical evidence to conclude that such disability may be associated with such exposure.

(b) VA shall not provide such care for a:

1. Disability which VA determines did not result from exposure to Agent Orange (see M-10, Pt. I).

2. Disease which the National Academy of Sciences has determined that there is limited or suggestive evidence of no association between occurrence of the disease and exposure to a herbicide agent. To date, those diseases include: skin cancer, gastrointestinal tumors, (stomach cancer, pancreatic cancer, colon cancer, rectal cancer), bladder cancer and brain tumors. *NOTE: VHA will promptly notify the field of any changes in this category.*

(c) This treatment authority expires after December 31, 2002.

THIS DIRECTIVE EXPIRES DECEMBER 3, 2001

VHA DIRECTIVE 96-073
December 2, 1996

(2) Ionizing Radiation Exposed Veterans

(a) Veterans who may have been exposed to ionizing radiation during nuclear testing, or during the occupation of Hiroshima and Nagasaki, have mandatory eligibility for hospital care and outpatient medical services, and discretionary eligibility for nursing home care for a disease:

1. Listed in 38 U.S.C. 1112(c)(2). To date, those diseases include leukemia (other than chronic lymphocytic leukemia), cancer of the thyroid, cancer of the breast, cancer of the pharynx, cancer of the esophagus, cancer of the stomach, cancer of the small intestine, cancer of the pancreas, multiple myeloma, lymphomas (except Hodgkin's disease), cancer of the bile ducts, cancer of the gall bladder, and primary liver cancer (except if cirrhosis or hepatitis B is indicated), cancer of the salivary gland, and urinary tract.

2. For which VA has recognized that there is credible evidence of a positive association between occurrence of the disease in humans and exposure to ionizing radiation. At this time VA recognizes: lung cancer, bone cancer, skin cancer, colon cancer, posterior subcapsular cataracts, non-malignant thyroid nodular disease, ovarian cancer, parathyroid adenoma, tumors of the brain and central nervous system, and rectal cancer (see M-10, Pt. II). *NOTE: Recognition of prostate cancer is in progress*

(b) This treatment authority is permanent.

(3) Persian Gulf War Veterans

(a) Veterans who may have been exposed to a toxic substance or environmental hazard while serving on active duty in the Southwest Asia theater of operations during the Persian Gulf War have mandatory eligibility for hospital care and outpatient medical services, and discretionary eligibility for nursing home care for any disability, notwithstanding that there is insufficient medical evidence to conclude that such may be associated with such exposure.

(b) VA may not provide such care for a disability that is found to have resulted from a cause other than the exposure described in the preceding (see M-10, Pt. III).

(c) This treatment authority expires after December 31, 1998.

3. **ACTION:** Network Directors and medical center Directors will provide health care to the veterans in accord with this directive.

4. **REFERENCE**

- a. Pub. L. 104-262, dated October 9, 1996.
- b. VHA Manual M-10, Part I, Agent Orange Health Care Services.

VHA DIRECTIVE 96-073
December 2, 1996

- c. VHA Manual M-10, Part II, Ionizing Radiation Health Care Services.
 - d. VHA Manual M-10, Part III, Persian Gulf Program.
5. **FOLLOW-UP RESPONSIBILITY:** The Office of Public Health and Environmental Hazards (13) is responsible for the follow-up of this directive.
6. **RESCISSION:** This VHA Directive will expire on December 3, 2001.

S/ by Thomas Garthwaite, M.D. for
Kenneth W. Kizer, M.D., M.P.H
Under Secretary for Health

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VHA DIRECTIVE 96-064
October 17, 1996

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 96-064
Change No. 1
November 8, 1996

PUBLIC LAW 104-262, VA HEALTH-CARE ELIGIBILITY RULES
EFFECTIVE OCTOBER 9, 1996

1. **PURPOSE:** The purpose of this Veterans Health Administration (VHA) change is to amend which zero percent service-connected veterans must agree to pay a copayment in order to be eligible for hospital care and outpatient medical services for the treatment of a nonservice-connected disability.
2. **POLICY:** Veterans who have a "*noncompensable*" zero percent service-connected disability requiring hospital care or medical services for a nonservice-connected disability must agree to pay a copayment to receive care.
3. **ACTION:** Under 2. **POLICY**, subparagraphs 2.b.(1), 2.b.(2), and 2.c, insert the word "*noncompensable*" before the word service-connected.
4. **REFERENCE:** Public Law 90-493, section 4(a) and 4(b).
5. **FOLLOW-UP RESPONSIBILITY:** Director, Headquarters Health Administration Service (161A), is responsible for this Directive. Questions may be referred to Roscoe Butler at 202-273-8302, or Anna Franks at 273-8305.
6. **RESCISSION:** VHA Directive 96-064 and this change will expire on November 1, 1997.

S/T. Garthwaite, M.D. for

Kenneth W. Kizer, M.D., M.P.H.
 Under Secretary for Health

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EXPIRATION DATE - NOVEMBER 1, 1997

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 96-064

October 17, 1996

**PUBLIC LAW 104-262, VA HEALTH-CARE ELIGIBILITY RULES
EFFECTIVE OCTOBER 9, 1996**

1. **PURPOSE:** The purpose of this Veterans Health Administration (VHA) Directive is to provide information for implementing Sections 101 and 103(a)(1) of Public Law (Pub. L.) 104-262, The Veterans' Health Care Eligibility Reform Act of 1996.
2. **POLICY:** Pub. L. 104-262 became effective on October 9, 1996. The law contains the following provisions which alter the way the Department of Veterans Affairs (VA) shall deliver hospital care, outpatient medical services, and nursing home care to the Nation's veterans. These provisions are to be implemented immediately.
 - a. Pub. L. 104-262 makes VA eligibility rules the same for both inpatient hospital care and outpatient medical services. The law repeals the former statutory requirement that certain care only be provided "in preparation for hospital admission or to obviate the need of hospital admission" or "to complete treatment incident to" hospital, nursing home, domiciliary, or outpatient care.
 - b. The law establishes two categories of veterans (as defined in Title 38 United States Code (U.S.C.) § 101) who are eligible for care. The first category includes veterans to whom VA "shall" furnish any needed hospital and outpatient care, but only to the extent and in the amount that Congress appropriates funds to provide the care. The second group includes veterans to whom VA "may" furnish any needed hospital and outpatient care, but only to the extent resources and facilities are available, and only if the veteran agrees to pay VA a copayment in exchange for care.
 - (1) The first eligibility group is composed of those veterans who were previously referred to as "Category A" veterans, (excluding zero percent service-connected veterans needing care for a nonservice-connected disability). This group is composed of the following:
 - (a) Veterans in need of care for a service-connected disability;
 - (b) Veterans who have a compensable service-connected disability;
 - (c) Veterans whose discharge or release from active military, naval, or air service was for a compensable disability that was incurred or aggravated in the line of duty;
 - (d) Veterans who are in receipt of, or who, but for a suspension pursuant to 38 U.S.C. § 1151 (or both a suspension and the receipt of retired pay), would be entitled to disability compensation, but only to the extent that such veteran's continuing eligibility for such care is provided for in the judgment or settlement provided for in Section 1151;

VHA DIRECTIVE 96-064
October 17, 1996

- (e) Veterans who are former Prisoners of War;
 - (f) Veterans of the Mexican border period or of World War I;
 - (g) Veterans who were exposed to Agent Orange in Vietnam, ionizing radiation, or environmental hazards in the Persian Gulf (care for this group is limited to certain disabilities possibly associated with exposure which will be detailed in a separate directive); and
 - (h) Veterans who have annual income and net worth below the currently existing "means test" threshold. **NOTE:** See *VHA Directive 96-004 dated January 24, 1996*.
- (2) The second group, those to whom VA "may" furnish care, includes all veterans not listed in the preceding paragraph 2b(1). This group is primarily nonservice-connected veterans with incomes and net worth above the currently existing "means test" threshold. Those veterans, previously called "Category C" veterans, must agree to pay copayments to receive care. This group includes zero percent service-connected veterans needing care for any nonservice-connected disability who are not otherwise eligible. Those veterans are required to agree to make copayments to receive care (they previously received care without a copayment requirement).
- c. Pub. L. 104-262 makes only one change to the rules governing the provision of nursing home care. Zero percent service-connected veterans receiving care in VA nursing homes are now required to agree to make copayments to receive their care, if not otherwise eligible.
 - d. Pub. L. 104-262 makes no changes to the rules governing the provision of domiciliary care in VA facilities.
 - e. Section 103 of Pub. L. 104-262 clarifies that VA has authority to provide preventive health services to eligible veterans even if they are not currently being treated for a disease or disability.
 - f. Section 103 of Pub. L. 104-262 eliminates a provision in prior law that prohibited VA from furnishing prosthetic devices and appliances on an outpatient basis. Section 103 provides that VA may furnish "sensori-neural aids" such as eyeglasses and hearing aids only pursuant to guidelines which VA must prescribe by regulation. A separate directive will be issued covering these changes.
 - g. Pub. L. 104-262 requires VHA to establish a patient enrollment system. Guidance on this will be provided at a later date.
3. **ACTION:** Veterans Integrated Service Network Directors and medical center Directors will provide health care to veterans in accord with this Directive.
4. **REFERENCE:** Pub. L. 104-262, dated October 9, 1996.

VHA DIRECTIVE 96-064
October 17, 1996

5. **FOLLOW-UP RESPONSIBILITIES:** Director, Headquarters Health Administration Service (161A). Questions may be referred to Roscoe Butler at (202) 273-8302, or Anna Franks at 273-8305.

6. **RESCISSION:** This VHA Directive will expire on November 1, 1997.

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 10/17/96
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**POST-HEARING QUESTIONS
CONCERNING THE FEBRUARY 11, 1997
HEARING ON PERSIAN GULF WAR VETERANS' ILLNESSES**

**FOR THOMAS L. GARTHWAITE, M.D.
DEPUTY UNDER SECRETARY FOR HEALTH
DEPARTMENT OF VETERANS AFFAIRS**

**SUBMITTED BY THE HONORABLE LANE EVANS
RANKING DEMOCRATIC MEMBER
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES**

Question 1: How many Gulf War veterans have applied for compensation?

How many Gulf War veteran compensation claims have been denied and what is the leading cause of denial?

Answer: As of February 1997, we had received compensation claims from 84,899 Persian Gulf War (PGW) veterans. Of these, 11,751 have claimed benefits for disabilities resulting from either undiagnosed illnesses or exposure to environmental hazards. There have been many reports of a "95 percent denial rate." The "95 percent denial rate" has been used to refer to the cases in which service connection for an undiagnosed illness was considered but not granted. However, statistics from our PGW tracking system currently show that 3,922 of these 11,751 veterans (33 percent) have been awarded service connection for some disability, whether or not related to an environmental hazard or an undiagnosed illness. At this time, we are in the midst of a readjudication of all undiagnosed illness cases identified in the tracking system. The readjudication will ensure that all Persian Gulf veterans have an opportunity to submit all types of evidence that may establish entitlement to service connection. It will also ensure that the information entered into the tracking system accurately reflects the final outcomes in these claims. As the readjudication progresses, we believe that the number 3,922 will increase significantly.

Denial of claims based on undiagnosed illnesses are presently categorized under one of the following reasons:

- (1) the disability is determined to be the result of a diagnosed condition;
- (2) the evidence indicates that the illness causing the disability is not chronic;
- (3) the disability has been found to be due to a reason unrelated to service in the Persian Gulf;
- (4) the disability did not manifest itself during service in the Persian Gulf or within the current 2-year presumptive period thereafter;
- (5) no disability is shown by the current evidence of record; and
- (6) the evidence indicates that a disability, first appearing within the presumptive period, has never been 10 percent disabling.

The leading cause of denial of undiagnosed illness claims has been reason number 4. In light of the President's recent approval of Secretary Brown's recommendation to extend the presumptive period through December 31, 2001, this will necessarily change.

Question 2: How many physical examinations for Gulf War compensation claims have been conducted by VA and non VA physicians?

Answer: I am sorry, but we do not maintain data responsive to either part of this question.

Question 3: How will VA respond to the Final Report of The President's Advisory Committee on Gulf War Veterans' Illnesses?

Answer: The Presidential Advisory Committee on Gulf War Veterans' Illnesses has provided a significant service to Persian Gulf veterans, and to those responsible for caring for them, by their in-depth review of the difficult issues of Gulf War veterans' illnesses. In January 1994, the President established the Persian Gulf Veterans Coordinating Board chaired by the Secretaries of VA and the Departments of Defense (DoD) and Health and Human Services (HHS). VA, under the auspices of the Coordinating Board, has submitted an action plan outlining the Departments' efforts, including those already partially or fully implemented, in response to the findings and recommendations of the Presidential Advisory Committee in their final report. The implementation plan addresses specific actions to be taken by VA, DoD, HHS, or the Coordinating Board in the areas of outreach, medical and clinical issues, research, coordination, investigations, and chemical and biological weapons agents. We have attached a copy of the implementation plan for your review (Attachment A).

Question 4: According to testimony given our Committee today, many veterans are not satisfied with either the attitude of VA or the treatment they're given when seeking health care. What action will you take to fix this problem?

Answer: As outlined in our written testimony, VA has been a leader in the development of health care programs, improvement of understanding concerning PGW health issues and dissemination of knowledge on Gulf War-related health issues. We believe that our programs are well-designed and comprehensive, but have not been uniformly delivered at all medical centers or by all health care providers. We also recognize that some Persian Gulf veterans have not received the kind of reception or care at VA medical facilities that we can be proud of. Testimony provided to the committee on February 11 gave examples of some of the problems which veterans encounter.

The Veterans Health Administration (VHA) is already working diligently to improve veterans' satisfaction with our services. VHA has established quality monitors and performance standards for the Registry program and is developing a new customer satisfaction survey for Persian Gulf veterans. These monitors address timeliness, access, and continuity of care. Some of Persian Gulf veterans have encountered difficulty getting continuity of follow-up for ongoing health problems after their Registry examination is completed. In order to address this concern, we have asked that each Persian Gulf veteran who has an ongoing need for medical care be assigned to a Primary Care Team. The Quality Management/Self-Assessment Monitor for 1996 shows that over three quarters of the Registry participants were assigned to primary care teams (Attachment B); in 1997 we hope that will be over 90 percent. We feel that this change will improve the satisfaction of veterans with their VA care.

In order to monitor the results of the implemented measures, we are establishing a Service Evaluation and Action Team (SEAT) within each Veterans Integrated Service Network. These programs will allow us to address veterans complaints and concerns on an ongoing basis, to collect data for quality improvement of our programs, and dynamically improve the high quality of care to veterans (Attachment C and D).

A key factor in the quality of care and veterans' confidence and satisfaction with that care is the knowledge and attitude of the health care providers who deliver that care. In order to keep our health-care providers well-informed on the latest developments, VA has utilized a wide array of communication vehicles including periodic nationwide conference calls, mailings, satellite video-teleconferences and annual on-site continuing medical education (CME) conferences. Our initial efforts were successful in educating a dedicated cadre of well-informed Registry

physicians and staff, and we will continue to keep them up-to-date on the latest developments. However, as mentioned in our testimony we see an opportunity to improve the understanding of Persian Gulf war-related health issues by other VA medical personnel. VA's goal is that all our health-care providers will have a working understanding of Gulf War exposures and health issues and will be able to discuss with their Persian Gulf patients how these issues could impact on their current or future health status. In order to meet this challenge and continue to improve our programs, the Veterans Health Administration has developed and will publish a self-study Persian Gulf CME program for every VA physician in early 1997.

Question 5: What are VA's plans to seek statutory authority to treat veterans and their families for reproductive health problems?

Answer: VA has no current plans to seek additional legislative authority to provide reproductive health care to Persian Gulf veterans and their families.

Section 107 of P.L. 103-446 did not grant VA general authority to treat or provide medical care to the spouses and children of Persian Gulf veterans. In addition, the study conducted under this section can only render data of limited scientific value, because of the inherent limitations of the required study design. More specifically, under section 107 of Public Law 103-446, VA medical evaluations can be offered to any individual who:

- is the spouse or child of a veteran, who (a) is listed in the Persian Gulf War Veterans Registry established under Public Law 102-585, and (b) is suffering from an illness or disorder;
 - is suffering from, or may have suffered from, an illness or disorder (including a birth defect, miscarriage, or stillbirth) which cannot be dissociated from the veteran's service in the Southwest Asia theater of operations; and
- has granted VA permission to include in the Registry relevant medical data from the evaluation.

Given the limited authority provided by this law, VA established a program that provides standardized medical evaluations and establishes a Registry database for health surveillance. The Department plans to analyze this database in a manner comparable to the VA Persian Gulf Registry database and the DoD CCEP database. This analysis will maximize our ability to compare the examination results of PGW veterans' spouses and children with the existing VA and DoD Persian Gulf health registries.

It should also be noted that VA's National Persian Gulf Veterans Health Survey is studying the health status of Persian Gulf veterans, their spouses and children, and VA will be providing physical examinations of veterans and family members during Phase III of this study. This randomized, controlled study will allow VA to assess the health status of Persian Gulf veterans and their families in a scientifically valid manner.

Question 6: I understand one of the ways you get information to your field facility staff is through teleconferencing. In Mr. Ford's testimony, he referenced a teleconference on Persian Gulf War issues that was poorly attended and stated the local Persian Gulf Registry Coordinator was not in attendance. How do you know that the latest information you are disseminating is getting to the local staff who need to know that information?

Answer: VA has used a variety of vehicles to educate and communicate with Persian Gulf Registry staff; these include telephone conference calls, quarterly mail-outs, satellite video-teleconferences and on-site continuing medical education (CME) conferences.

Clinical care responsibilities sometimes interfere with 100 percent participation of Persian Gulf staff. In recognition of this fact, minutes are produced for the conference calls and videotapes are made available from each satellite broadcast. The minutes are included in quarterly mail-outs for review by the Registry staff. Videotapes are provided to each medical center library so that personnel can review the programs at a later date if they miss the original broadcast.

The satellite video-conference which Mr. Ford referred to in his testimony was a program on the events at Khamisiyah and potential health effects of chemical warfare agents. In order to provide timely information to health care providers, the program was produced and broadcast with short notice. Some medical centers were not able to reschedule staff activities so that they could participate during the broadcast. However, Chiefs of Staff were provided a copy of the videotape and asked to ensure that medical staff viewed the program and were knowledgeable on this important subject (Attachment E).

Persian Gulf program performance measures require at least 75 percent or greater staff participation in education calls and conferences (Attachment F). VHA will continue to encourage and monitor full participation of health care providers in CME activities.

Question 7: It is my understanding Dr. William Baumzweiger, a fellow at the West Los Angeles Outpatient Clinic, has been very outspoken about this theory and treatment of Persian Gulf War veterans. What is the status of Dr. Baumzweiger's fellowship and your opinion of his theories and treatment methodologies. Identify all changes VA has made regarding the role and responsibilities of Dr. Baumzweiger in providing VA health care and particularly his provision of health care to Persian Gulf veterans.

Answer: William E. Baumzweiger, M.D., is currently a Neurology Fellow at the VA Outpatient Clinic in downtown Los Angeles (LAOPC--351 Temple Street). This Fellowship position is a training position, in which Dr. Baumzweiger is appointed as a fifth-year resident. As such, he does not have clinical privileges and cannot practice independently. Prior to pursuing Neurology training, Dr. Baumzweiger, who is a board certified psychiatrist, practiced psychiatry in the private sector for approximately twenty years.

Dr. Baumzweiger's Fellowship appointment is for one academic year, beginning July 1, 1996, and ending June 30, 1997. The purpose of the Neurology Fellowship is to obtain advanced training in neuromuscular diseases and disorders, including performance of electromyography (EMG), testing of a muscle to determine how well the muscle is working. At this time, it appears Dr. Baumzweiger will complete his Fellowship on June 30, 1997.

There are presently over 90 federally supported Persian Gulf War (PGW) research studies. VA has been, and will continue to be, open to all research, diagnostic and treatment approaches that are ethically and scientifically based. However, our highest commitment must continue to be ensuring quality, appropriateness and continuity of care.

Dr. Baumzweiger's work to date can be described as clinical case review, or a case series report. At the time Dr. Baumzweiger presented his clinical findings and his hypotheses concerning brainstem dysregulation syndrome on September 17, 1996, to the Persian Gulf Research Working Group, he was advised to publish his case series in a peer-reviewed journal and to prepare and submit a research protocol to investigate his untested hypothesis. This is the route Dr. Haley followed when he published evidence to support his hypothesis about organo-phosphate induced delayed polyneuropathy. The work of Dr. Abou-Donia, which provided a scientific basis for this work, was published in the toxicology literature and has been discussed in the research community for over a year. This is an ongoing area of investigation and research which will benefit from the work of many researchers. It is important to continue to stress that all hypotheses need to be subjected to peer review and clinical validation.

Regarding changes VA has made in Dr. Baumzweiger's role and responsibilities, the situation at present is as follows:

1. Dr. Baumzweiger is currently continuing his Fellowship training, under the supervision of C. Puckett-Robinson, M.D., Chief, Neurology Service, LAOPC.
2. Dr. Baumzweiger has cooperated with Dr. Puckett-Robinson and LAOPC's senior management team to transition his PGW veterans for reassignment to staff

physicians and inclusion in LAOPC's Persian Gulf War registry and protocol. This will ensure that these veterans, approximately 13 in number:

- a. Have their medical care appropriately supervised by staff physicians and LAOPC's PGW Coordinator. This includes proper documentation of their care and medications in paper and electronic records, which is especially important for patients who had been coming from far away (i.e., Utah, Texas and Idaho).
- b. Have more extensive access to VA's PGW programs, and referrals as necessary and as appropriate for clinical consultations, such as cardiology, orthopedics, neurology, infectious diseases, gastrointestinal medicine and mental health. Referrals will include, as necessary, consultation with specialists at the nearby VA Medical Center in West Los Angeles (Wilshire Boulevard), which is one of VA's regional referral centers for PGW veterans.
- c. Have their LAOPC PGW treatment, including medications, identified to their local VA or non-VA physicians, for the "long distance" patients.

Question 8: In reviewing the Persian Gulf Registry records for veterans who were possibly within 50 kilometers of Khamisiyah Ammunition Storage Area during the demolition in March 1991, you testified 81 registry participants were diagnosed with musculoskeletal conditions at a higher rate than the 50 kilometer or general registry group. Dr. Garthwaite, you testified a review of the CCEP participants which were within 50 kilometers of Khamisiyah reports symptoms similar to other Army CCEP participants. Please explain.

Answer: The Department of Defense reported to VA that their preliminary analysis of the Comprehensive Clinical Evaluation Protocol (CCEP) health records of individuals identified as part of the demolition team and within 50 kilometers of Khamisiyah during March 1991 showed no apparent differences in health compared to the general CCEP participants. This information is based on self-selected, voluntary health examinations and should not be considered conclusive. DoD is surveying service members believed to be in the area of Khamisiyah in March 1991 in order to better identify the troops who were potentially exposed to subclinical levels of nerve agents. DoD will also sponsor appropriate epidemiologic research on this group to better understand their current health status. No definitive conclusions can be drawn from the currently available health surveillance data however, the preliminary data do not indicate that veterans in the CCEP or VA PGW registries are suffering from an increased rate of neurologic or cognitive conditions which could possibly result from acute toxic exposures to nerve agents.

**POST-HEARING QUESTIONS
CONCERNING THE FEBRUARY 11, 1997
HEARING ON PERSIAN GULF WAR VETERANS' ILLNESSES**

**FOR THOMAS L. GARTHWAITE, M.D.
DEPUTY UNDER SECRETARY FOR HEALTH
DEPARTMENT OF VETERANS AFFAIRS**

**SUBMITTED BY THE HONORABLE LUIS GUTIERREZ
MEMBER, SUBCOMMITTEE ON HEALTH
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES**

Question: Dr. Garthwaite, as we discussed earlier, 95 percent of Persian Gulf veterans who have "undiagnosed illnesses" are denied service-connection by the VA.

While I am impressed with many of the VA programs for Gulf War vets that you described in your testimony, I fail to understand how 95 percent of all Desert Storm vets are failing to get service-connection by the VA.

Dr. Garthwaite, I can't help but feel that the VA is letting too many of these veterans down, and so far I have not heard a valid reason for why this is happening.

I know the two-year presumptive period had kept many Gulf War vets from getting the care they need and I believe it should be extended.

Can you comment as to the rationale for the denial of service-connection to so many veterans of the Gulf War?

Answer: It is not entirely accurate to state that "95 percent of Persian Gulf veterans who have 'undiagnosed illnesses' are denied service connection by the VA." It is incorrect to state further that "95 percent of all Desert Storm veterans are failing to get service-connection by the VA."

As of February 1997, we had received compensation claims from 84,899 Persian Gulf War (PGW) veterans. Compensation has been awarded to 27,868 PGW veterans (33 percent). Another 37,921 (45 percent) have service-connected disabilities rated as zero percent disabling, for which no compensation is payable. Therefore, the claims of only 19,110 PGW veterans (23 percent) have been completely denied (no compensation and no zero-percent service connection.)

Among the 84,899 PGW veterans, 11,751 have claimed benefits for disabilities resulting from either undiagnosed illnesses or exposure to environmental hazards. Service connection has been awarded to 1,611 of them; 753 are service connected for disabilities resulting from undiagnosed illnesses. The "95 percent denial rate" has been used to refer to the cases in which service connection for an undiagnosed illness was considered but not granted. However, statistics from our PGW tracking system currently show that 3,922 of these 11,751 veterans (33 percent) have been awarded service connection for some disability, whether or not related to an environmental hazard or an undiagnosed illness. At this time, we are in the midst of a readjudication of all undiagnosed illness cases identified in the tracking system. The readjudication will ensure that all Persian Gulf veterans have an opportunity to submit all types of evidence that may establish entitlement to service connection. It will also ensure that the information entered into the tracking system accurately reflects the final outcomes in these claims. As the readjudication progresses, we believe that the number 3,922 will increase significantly.

Denial of claims based on undiagnosed illnesses are presently categorized under one of the following reasons:

- (1) the disability is determined to be the result of a diagnosed condition;
- (2) the evidence indicates that the illness causing the disability is not chronic;

(3) the disability has been found to be due to a reason unrelated to service in the Persian Gulf;

(4) the disability did not manifest itself during service in the Persian Gulf or within the current 2-year presumptive period thereafter;

(5) no disability is shown by the current evidence of record; and

(6) the evidence indicates that a disability, first appearing within the presumptive period, has never been 10 percent disabling.

The leading cause of denial of undiagnosed illness claims has been reason number 4. In light of the President's recent approval of Secretary Brown's recommendation to extend the presumptive period through December 31, 2001, this will necessarily change.

In regard to medical care, all PGW veterans are by statute eligible to receive treatment for conditions that might possibly be the result of exposure to a toxic substance or environmental hazard during service in the Gulf. This is separate from entitlement to service connection and unrelated to the length of the presumptive period.

ATTACHMENT A
(THE HONORABLE LANE EVANS)

Persian Gulf Veterans Coordinating Board



Department of Defense



Department of Health and Human Services

Department of Veterans Affairs



MAR 7 1997

The President
The White House
Washington, DC 20500

Dear Mr. President:

The Departments of Defense (DoD), Veterans Affairs (VA) and Health and Human Services (DHHS) appreciate the effort, thought and constructive input provided by the Presidential Advisory Committee on Gulf War Veterans' Illnesses in its final report.

We are pleased to submit to you our implementation plan for the recommendations contained in the final report of the Presidential Advisory Committee on Gulf War Veterans' Illnesses. This plan represents many hours of careful consideration of the Advisory Committee's recommendations. The plan was developed, coordinated, and consolidated with the assistance of the Persian Gulf Veterans Coordinating Board, which we jointly co-chair. Action is already underway to implement the recommendations.

Respectfully,

WILLIAM S. COHEN
Secretary of Defense

acting

DONNA E. SHALALA
Secretary of Health
and Human Services

JESSE BROWN
Secretary of
Veterans Affairs

EXECUTIVE SUMMARY

**The Persian Gulf Veterans Coordinating Board Action Plan
with Respect to the Findings and Recommendations of the Presidential Advisory
Committee on Gulf War Veterans' Illnesses Final Report**

The Persian Gulf Veterans Coordinating Board comprised of the Secretary of Defense (DoD), Health and Human Services (DHHS), and Veterans Affairs (VA) greatly appreciate the effort, thought and constructive recommendations provided by the Presidential Advisory Committee on Gulf War Veterans' Illnesses in its final report.

Like the Presidential Advisory Committee, the three Departments recognize that the issues surrounding Gulf War veterans' illnesses are complex. Since the end of the Gulf War, concerns have been raised as to whether there is a relationship between the illnesses (diagnosed and undiagnosed) being experienced by some Gulf War veterans and their family members and a variety of possible hazardous exposures during service, including chemical warfare agents. We share these concerns and are taking concrete steps to determine the causes of these illnesses and to provide care for veterans who are ill.

The Presidential Advisory Committee's "Final Report" provides a number of important findings and valuable recommendations. This plan outlines the Departments' actions, including those already partially or fully implemented, taken in response to the findings and recommendations of the Presidential Advisory Committee in their "Final Report." This Action Plan is a dynamic document which will need to be revisited and adjusted as information becomes available and we learn more. Furthermore, in the upcoming weeks, the three Departments and the Persian Gulf Veterans Coordinating Board will develop specific timelines for the actions proposed.

The plan addresses actions to be taken in the areas of outreach, medical and clinical issues, research, coordination, investigations, and chemical and biological weapons. These actions include:

- Initiation of a Presidential Review Directive pursuant to which the National Science and Technology Council will create an interagency plan to address health preparedness for, and readjustment of, veterans and their families after future conflicts and peacekeeping missions.
- The Persian Gulf Veterans Coordinating Board's Clinical Working Group will develop a comprehensive risk communication plan. Government and non-government risk communication experts will be engaged to assist in development and implementation of the plan.

- VA Transition Assistance Program briefings for service members separating from active duty will emphasize the VA programs and services available to Gulf War veterans and their families.
- VA will ensure that its outreach to the Latino populations provides information on Gulf War-related programs. A Spanish language information pamphlet and federal veterans benefits guide are being produced.
- Re-evaluation and enhancement of the Persian Gulf Veterans Coordinating Board will include the addition of new members to the existing Clinical, Research, and Compensation Working Groups. Further, a Deployment Planning Working Group will be established to make recommendations for interagency activities, and to monitor pre-deployment, deployment, and post-deployment medical surveillance programs.
- The Food and Drug Administration is preparing regulations that will solicit public and expert comment on any rule that permits waiver of informed consent for use of investigational products in military exigencies.
- Deployment health surveillance programs will be carried out involving pre-deployment health screening and education, deployment operational, environmental, and medical surveillance, and post-deployment health surveillance and risk communication.
- DoD is developing enhanced orientation and training procedures to inform service personnel about the health risks, benefits and proper use of military medical countermeasures to chemical and biological warfare agents.
- Military medical record keeping will be given particular priority by DoD officials at the highest levels. Computerized medical records, medtags, and compatible information systems are under development.
- Continuing medical education programs for health care providers in VA and DoD will be enhanced to ensure up-to-date patient education and delivery of high quality health care.
- DoD is developing a Directive on Combat Stress that will set forth policy, improve stress reduction and management programs, and involve military leadership in stress management and unit cohesion programs.
- DHHS will engage in a special effort designed specifically to impact the stigmatization of stress-associated and other mental health conditions.
- DoD has established the Office of the Special Assistant for Gulf War Illnesses, which is responsible for investigation of reported Gulf War-related incidents that may have health consequences. This effort involves case management and release of investigation narratives, and outreach to veterans and Military Coalition organizations. Recent activities include initiation of a Khamisiyah survey to collect information from veterans who were there and to encourage them to participate in the health registries.
- Service members who may have been exposed at Khamisiyah and other sites will be notified and any needed evaluation and care provided; moreover, appropriate research will be conducted.
- Research activities are a key component of the government's response. Related initiatives include:
 - The Persian Gulf Veterans Coordinating Board has encouraged Public Advisory Committees be established for all large epidemiologic studies;

- Federal research requests for proposals include:
 - the possible long-term health effects of chemical and other hazards (including subclinical exposure to chemical warfare nerve agents);
 - studies of combined exposures to pyridostigmine bromide, pesticides and other agents;
 - epidemiologic feasibility studies on Khamisiyah veterans and other groups possibly exposed to low-level chemical agents; and
 - research on stress-related disorders
- Development of a strategic plan for research into the potential health consequences of exposure to chemical and other hazards, including low-levels of chemical warfare agents; and
- Support for long-term mortality studies and cancer registries.

The Persian Gulf Veterans Coordinating Board has engaged in a comprehensive, coordinated effort to respond to the health concerns of Gulf War veterans. DoD, DHHS and VA are committed to finding answers to Gulf War illnesses and look forward to working with the Presidential Advisory Committee on Gulf War Veterans' Illnesses to achieve this goal. Our veterans and their families deserve no less.

**THE PERSIAN GULF VETERANS
COORDINATING BOARD
ACTION PLAN**

WITH RESPECT TO

THE FINAL REPORT OF

**THE PRESIDENTIAL ADVISORY COMMITTEE ON
GULF WAR VETERANS' ILLNESSES (PAC)**

CHAPTER 2: THE GOVERNMENT'S RESPONSE

Findings and Recommendations Regarding Outreach

Finding 2-1: In their geographic areas, Vet Center staffs have established working relationships with the veterans community, veterans service organizations, local municipal and state veterans liaison offices, in-region Guard and Reserve units, community social services organizations, local Department of Veterans Affairs (VA) medical center personnel, and military establishments. These relationships enable Vet Centers to provide education and outreach to local communities about issues and clinical programs concerning Gulf War veterans, and a significant number of Gulf War veterans use their services.

Finding 2-2: The outreach initiative of VA's Persian Gulf Family Support Program was an effective method of communicating information about Gulf War veterans illnesses--in particular the established government clinical programs--to veterans, Reservists, National Guard members, and local communities. The outreach component used trained, knowledgeable personnel in the field to establish a communication network with the community and deliver specific information directly to Gulf War veterans.

Recommendation: Department of Defense (DoD) and VA should follow the model of field-based outreach demonstrated in the Vet Centers and the Persian Gulf Family Support Program when developing health education and risk communication campaigns for active duty service members, Reserve and Guard personnel, and other veterans. General, less specific outreach methods--e.g., hotlines and public service announcements--should be viewed as an important supplement, but not as replacements.

Response: Concur. After the conclusion of the Persian Gulf War in 1991, Vet Center services were made available to those who served in the Persian Gulf. These Vet Centers had seen over 25,000 Persian Gulf veterans by the summer of 1992. This prompt response by the Vet Centers to the acute Post-Traumatic Stress Disorder (PTSD) and other post-war readjustment difficulties, such as family and employment problems, illustrates VA's commitment to early intervention and outreach. As of September 30, 1996, Vet Centers had seen more than 74,000 Persian Gulf veterans.

VA can apply the same successful Vet Center strategy of targeting specific veteran populations, developing intensive networks, and creating referral relationships with other community agencies to formulate health education and risk communication campaigns. These field-based risk communication and health education outreach programs will be directed specifically at Persian Gulf veterans, and Reserve and Guard personnel. Persian Gulf veterans and their families will be invited to participate, as appropriate, in future VA outreach and focus sessions,

so VA can provide them with risk communication and health education information and learn more about their health care needs.

VA's annual National Training Program conferences update VA medical center Persian Gulf Registry physicians, health care professionals, and Vet Center service providers on the latest information available from the clinical and scientific studies of Persian Gulf veterans' illnesses. Risk communication and health education issues will continue to be included in future National Training Program continuing medical education conferences. VA health care providers attending these conferences will be able to recognize the most common symptoms and diagnoses of Persian Gulf veterans and communicate potential health risks of Gulf War service to their patients.

DoD agrees that a strengthened "field-based" outreach system is needed to address post-deployment follow-up. Likewise, DoD has in place an extensive system available for outreach to active duty service members and their families and to Reserve and Guard personnel who are currently associated with DoD. DoD is committed to better using that system, including the command structure, both for Gulf War veterans and for future post-deployment follow-up. As one example, with respect to active duty personnel and their families, DoD will use the Family Service Centers which can achieve the effectiveness of the VA field-based model. Liaison between the Assistant Secretary of Defense (ASD)/Health Affairs and the ASD(Force Management Policy)/Personnel Support, Families and Education will result in a more effective strategy to use existing organizational resources to ensure appropriate dissemination of information. DoD will also make better use of its health personnel with respect to health education and risk communication. These health personnel, including frontline medics, are located throughout the world with our active duty personnel and are supporting active duty personnel and their families on a daily basis.

The Office of the Special Assistant for Gulf War Illnesses has in place an outreach office which aggressively performs call-backs to follow-up on hotline calls. This is the first over-arching DoD effort to establish two-way communication in the form of a true dialogue versus only receiving information. These call backs not only provide an in-depth debrief, but also, a single point of contact between the Office of the Special Assistant for Gulf War Illnesses and the reporting Gulf War veteran for the future. The process involves the veteran in the incident investigation process in a significant and meaningful way. DoD's medical treatment facilities (MTFs) at military installations nationwide offer medical outreach and treatment for Gulf War veterans. As service members call the Comprehensive Clinical Evaluation Program (CCEP) Hotline, their first call-back is from the nearest MTF to schedule their evaluation.

DoD is in the process of developing a new more proactive GulfLINK website to include adding a Frequently Asked Questions (FAQ) page to address some of the common concerns of those who served in the Gulf, their family members, and the general public. Two-way E-mail will also be added to GulfLINK to allow users to quickly query experts from the Office of the Special

Assistant and receive an expeditious reply. The intent is to publish all available public information as well as periodic status reports on investigations in progress in a timely manner.

DoD will employ nationally recognized experts in the field of risk communications to develop a DoD strategic plan that is: (1) fully coordinated and integrated with the Persian Gulf Veterans Coordinating Board (PGVCB) plan; (2) provides for the conduct of risk communication training for all DoD personnel involved with direct public interface; (3) seeks the advice of experts on specific events or issues affecting our veterans; and, (4) allows for the review of all products to ensure the most effective dissemination of information. Additionally, DoD recognizes that feedback is an important aspect of risk communication and will ensure the measures are in place to evaluate the effectiveness of this communication plan.

VA has a long-standing relationship and communication network with Veterans Service Organizations (VSOs). Additionally DoD's Office of the Special Assistant for Gulf War Illnesses is establishing relationships with member organizations of the Military Coalition that are critical to providing information at the local level. The objective is to share information with the Military Coalition Organizations (MCOs) nationwide, and to invite their participation in information-sharing, investigations and a search for solutions process. This includes encouraging publications of information in Military Coalition organization newsletters and magazines, presentations and briefs, and demonstrations of military equipment that pertains to the detection and identification of chemical warfare agents.

The PGVCB will incorporate these activities into the comprehensive risk communication plan.

Finding 2-3: Ninety percent of separating active duty service members attend Transition Assistance Program (TAP) workshop briefings conducted jointly by DoD, VA, and DOL. VA benefits briefings during the TAP workshop could be an effective method of outreach about DoD and VA programs for evaluating Gulf War veterans illnesses, yet there is no evidence their clinical programs receive mention.

Recommendation: VA should direct its Transition Assistance Program workshop benefits counselors to specifically mention DoD and VA programs related to Gulf War veterans' illnesses.

Response: Concur. The outcome outlined by the recommendation is a part of Veterans Benefits Administration's (VBA) transition assistance briefings. We agree that VA benefits briefings conducted in association with TAP workshops are an effective method of outreach to Gulf War veterans. To ensure the effectiveness of these briefings, the Veterans Services Program Staff (VSPS) (which is responsible for TAP administration within VA) provides Military

Services Coordinators (MSCs) with materials and/or guidance related to briefing content.

The VSPS has previously directed MSCs to include Gulf War issues in their benefit presentations. In addition, VSPS creates and distributes overheads, photographic slides, fact sheets, and pamphlets for use in benefit presentations. The latest version of the slides includes a series covering the following Persian Gulf War issues: (1) disability compensation for undiagnosed illnesses; (2) the types of evidence needed to support compensation claims for undiagnosed illnesses; (3) other VA programs or services available to Gulf War veterans and their families; and, (4) toll-free numbers that service members may call for more detailed information and assistance.

The VSPS has distributed a revised set of transparencies to MSCs which provide more information about VA and DoD programs for Gulf War veterans. These transparencies stress the importance of continued discussion of VA and DoD programs for Gulf War veterans during benefit briefings.

DoD supports this approach and the DoD Director of Transition Support and Services will coordinate with the VA and help ensure that information on DoD and VA clinical Persian Gulf veterans health care and compensation programs is effectively provided to separating active duty service members. The Compensation and Benefits Working Group of the PGVCB will monitor this process and explore options for improvement.

Finding 2-4: Through the initiatives of the Women Veterans Health Programs, VA has implemented a range of efforts to inform women veterans about available health services.

Recommendation: VA should ensure that its initiatives under the Women Veterans Health Programs specifically provide information about Gulf War-related programs.

Response: Concur. Operations Desert Shield and Desert Storm involved the largest deployment of women to a war zone in our nation's history; women composed 7 percent of the approximately 697,000 deployed troops. VA's Office of Public Health and Environmental Hazards is the Veterans Health Administration (VHA) program office for both the Women Veterans Health and Persian Gulf Veterans Programs. In the past, the Office has coordinated VA program planning in these two areas. VHA is committed to long term continuation of these efforts as they relate to medical care, research, outreach and education for women who served in the Persian Gulf War. Information will be included regarding Gulf War-related women veterans' programs in both Persian Gulf and Women Veterans Health communications and education programs in May and June 1997.

The Clinical Working Group (CWG) of the PGVCB will monitor these efforts and explore options for improvement.

Finding 2-5: In regions with significant Latino populations, Veterans Centers and VAMCs deliver bilingual, cross-cultural outreach services.

Recommendation: VA should ensure that its outreach to Latino populations specifically provides information about Gulf War-related programs.

Response: Concur. In 1996, VA published and distributed copies of the first Spanish language version of *Federal Benefits for Veterans and Dependents* entitled "*Beneficios Federales Para Veteranos y Sus Dependientes*." The Spanish language benefits book was distributed to all VA Regional Benefits Offices and VA Medical Centers with significant Latino populations. This booklet provides information regarding compensation benefits for chronically disabled veterans who suffer from undiagnosed illness believed to be the result of their service in the Gulf. In addition, Gulf War veterans are informed about the Persian Gulf War Registry Program and special eligibility for any Persian Gulf War veteran who may have been exposed to a toxic substance or environmental hazard during the Gulf War. The Spanish language version of the benefits book also lists the Persian Gulf Veterans information phone number (800-PGW-VETS). VA will redistribute a 1997 version of the Spanish language benefits book later this year. VA will also conduct Spanish language print, radio and television interviews designed to inform Gulf War veterans of their benefits as well as update them on VA's research agenda. In addition, VA is developing a new information pamphlet for Gulf War veterans that will be distributed in English and Spanish by Summer 1997.

Finding 2-6: While newspaper articles and television and radio broadcasts disseminated by DoD's American Forces Information Service provide adequate media coverage of Gulf War illnesses-related issues, few of the media products perform the outreach functions of publicizing government-sponsored Gulf War veterans clinical programs and methods of referral into them.

Recommendation: As the Committee stated in its *Interim Report*, DoD and VA should develop and utilize more refined performance measures to determine how well outreach services are reaching concerned parties. DoD and VA officials (specifically those in the Armed Forces Information Service and its broadcasting arm, the Armed Forces Radio and Television Service) using media products for outreach initiatives should be aware of the difficulty in enumerating the actual readership and viewership figures and be concerned about how effectively their message saturates the targeted population.

Response: Concur. VA conducted a Gulf War Veterans Public Service Announcement (PSA) campaign in 1995 consisting of video, radio and print

announcements. The Committee's *Interim Report* recommended that the content of the announcements be more specific regarding services available to and illnesses suffered by Gulf War veterans. VA revised the PSAs and conducted another outreach campaign in 1996. VA hired a media marketing firm to distribute the print, radio and television PSAs and provide follow-up reports to VA regarding market penetration. In addition, VA purchased satellite time to conduct one-on-one interviews with television stations in the country's top media markets. These interviews afforded VA prime time viewership and provided substantial outreach to Gulf War veterans and their families. VA's Regional Public Affairs Offices will continue to augment its outreach effort by placing news articles in regional media outlets to inform veterans and their families of available benefits. Since the *Interim Report*, the VA Persian Gulf Helpline has begun to collect data on how veterans heard about that service. A summary will be provided to the Committee.

In late FY 96, DoD conducted a survey that addressed the awareness of the CCEP and the Gulf War Incident Hotline in a representative sample of 54,000 active duty and retired active duty Gulf War veterans. This survey indicated that a relatively low proportion of active duty and retired active duty Gulf War veterans are aware of the CCEP and the Incident Hotline. The survey findings will be useful in designing more effective communication strategies for future outreach efforts. DoD agrees that there is a need to assess which communications mechanisms are most effective for reaching Gulf War veterans and will continue to do so in cooperation with the PGVCB.

A critical element of DoD's new Office of the Special Assistant for Gulf War Illnesses is a public affairs/public outreach arm that is focused on reaching the public through the organizations of the Military Coalition command information programs and media channels. One of the primary charters of public outreach is to develop an effective dialogue and to solicit feedback from veterans. The Office of the Special Assistant will develop an assessment of all means of reaching out and informing the public to include Armed Forces Information System (AFIS) and the Armed Forces Radio and Television Service (AFRTS). This will be a part of DoD's strategic public affairs plan and risk communication strategy as previously discussed (response to 2-2). AFIS is a primary channel for disseminating information to active duty and reserve component service members and their families. The information provided by AFIS and used in installation and activity newspapers is available to all uniformed and civilian personnel departmentwide. In addition, AFRTS is available to service members and DoD civilians at 156 overseas locations and aboard ships at sea. The CCEP toll-free number has been publicized through the Armed Forces Radio and Television Service, and has been reported in over 1,100 DoD publications around the world. AFIS is also available via the Worldwide Web. The CCEP hotline number will continue to be publicized in numerous AFIS print and broadcast products. We will continue to make our target audiences aware of the toll-free number and other important information on Gulf War Illnesses.

These efforts will be incorporated into the PGVCB's comprehensive risk communication plan.

Finding 2-7: DoD's 1996 *Internal Information Plan--Persian Gulf Illnesses* describes its Comprehensive Clinical Evaluation Program, yet fails to provide the most basic information on how to register for it.

Recommendation: DoD should reissue its *Internal Information Plan* on Gulf War-related illnesses. It should make a special effort to note the revision provides the toll-free number and that individuals are encouraged to register for its Comprehensive Clinical Investigation Program (CCEP). It also should take the opportunity to provide updated information.

Response: Concur. The AFIS Internal Information Plan (IIP) is a management plan which lists broad topic areas to be addressed by DoD internal information media during the year. Topics for FY 96 included subjects such as recycling, the flag, child abuse and financial management. One page was allocated to each topic. Gulf War illnesses will be included as a major focus in next year's plan. Additional public affairs guidance on encouraging service members to register in the CCEP, how to register and publication of the toll-free number will be issued.

The PGVCB risk communication plan will incorporate information on registration for clinical examinations.

Recommendation: In an attempt to increase veterans' and the public's awareness and understanding of the full range of the government's commitment to addressing the nature of Gulf War veterans' illnesses, DoD and VA should reevaluate the goals and objectives of their risk communication efforts. DoD and VA should develop effective methods that provide the affected community with comprehensive information concerning possible exposures to environmental hazards, potential health effects from risk factors, and explanations of ongoing and completed clinical and epidemiologic studies.

Response: Concur. VA, DoD and the Department of Health and Human Services (DHHS) will collaborate, through the PGVCB, to refine goals and objectives and develop more effective methods for risk communication regarding Gulf War veterans' illnesses. Risk communication will address possible exposure to hazards (chemical, biological, and environmental hazards), explain potential health effects from these risk factors, and provide information on studies on potential health risks and how to respond to those risks. In that effort, DoD and VA will involve DHHS and their risk communication experts as well as using the expertise of nationally recognized experts in the field of risk communications.

Since June 1996, when the Defense Department first learned of the potential exposure of our troops to chemical agents during the destruction of

ammunition and equipment at Khamisiyah, DoD has conducted an extensive multimedia campaign designed to inform soldiers and veterans of the events at Khamisiyah. Our coordinated and expanded outreach program asking soldiers to provide information of their experiences at or near Khamisiyah and encouraging them to seek assistance for health problems they believe may be a result of their service in the Persian Gulf has been well-received, providing much new information and involving thousands more veterans in the process.

In order to accomplish these goals, the PGVCB CWG will conduct a day-long conference with risk communication experts to design a Gulf War veteran risk communication plan. The plan will take into account the size and location of the Gulf War veteran population and the existing communications tools of the Departments including direct mail, newsletters, radio, print and television media. The goal of the CWG will be to develop a risk communications plan that will be effective communicating with Gulf War veterans and their families regarding information on possible exposures to environmental hazards, potential health effects, treatment options and ongoing research. The plan will be submitted to the Committee by May 1, 1997.

Finding 2-8: Effective risk communication is essential to the government's credibility on Gulf War veteran's illnesses, but DoD and VA have not seriously attempted to educate veterans about health effects of service in the Gulf War or to establish a dialogue concerning research programs relevant to veterans' concerns.

Finding 2-9: Several federal agencies have developed, tested, and validated techniques for health risk communication that could be adopted by DoD and VA.

Recommendation: DoD and VA should immediately develop and implement a comprehensive risk communication plan. This effort should move forward in close cooperation with agencies that have a high degree of public trust and experience with risk communication, such as the Agency for Toxic Substances and Disease Registry (ATSDR) and the National Institute for Occupational Safety and Health.

Response: Concur. The PGVCB will develop and implement a comprehensive risk communication plan within the next six months. The Board recognizes that substantial expertise exists within DHHS at the ATSDR, and National Institute for Occupational Safety and Health (NIOSH), and will be collaborating with these agencies as well as using the expertise of nationally recognized experts in the field of risk communications.

Recommendation: Because health risk information and education applies to service members who remain on active duty and veterans no longer in military service, DoD and VA should closely coordinate the federal government's risk communication effort for Gulf War veterans and other members of the affected community. Departmental

commitments to any plan should be viewed as continuous and long-term; a sustained effort is particularly critical in light of veterans' and public skepticism arising from the recent revelations related to chemical weapons.

Response: Concur. The PGVCB agrees that the risk communication must be coordinated, forward-looking, and dynamic with a commitment to long-term and sustained communication to our Gulf War veterans.

DHHS, DoD and VA will work closely in sharing information. For example, the PGVCB's CWG will provide their plain language fact sheets for dissemination to veterans, family members and other interested parties on Gulf War-related topics. Copies of these materials will be sent to the Committee for review by May 1, 1997. DoD will make available the narratives on investigative activities as they become available.

Recommendation: In its coordinated risk communication plan, DoD and VA should engage MCOS and veterans service organizations as intermediaries--and include personnel in leadership positions, such as senior enlisted personnel (for active duty military) and state veterans' service officials--in the effort to establish an efficient information exchange process where veterans receive accurate information and the departments receive valuable feedback on clinical programs, health concerns, and communication efforts.

Response: Concur. VA and DoD are working towards development and implementation of a comprehensive risk communication plan within the next six months and with advice and assistance from ATSDR and NIOSH.

VA and DoD will closely coordinate the federal government's comprehensive plan for disseminating clinical and epidemiological information to members of the affected community and other interested parties through the interagency PGVCB. The PGVCB's CWG is currently developing fact sheets on Gulf War-related issues for this purpose. The CWG and Research Working Group (RWG) will collect information from clinical investigations, epidemiological studies and basic research findings for dissemination to veterans, health-care providers, researchers, and the general public. VA and DoD view these risk communication efforts as a continuous long-term process, and will maintain the activities necessary for accomplishing these objectives as long as the need exists.

VA and DoD agree that their coordinated risk communication plan should engage veterans service organizations and include personnel in leadership positions, such as senior enlisted personnel (for active duty military) and state veterans service organization officials in the effort to establish an efficient information exchange process where veterans receive accurate information and the departments receive valuable feedback on clinical programs, health concerns, and communication efforts. VA has long recognized the importance of involving "stakeholders" in developing health-care programs and, along with DoD, will

utilize this process for designing a comprehensive risk communication plan. VHA will continue to use its monthly liaison meeting with veterans service organizations to seek their advice and guidance, and receive feedback on clinical programs, health concerns, and communication efforts. VSO representatives serving on VA's Persian Gulf Expert Scientific Committee also serve as intermediaries in the information exchange process.

In the interests of both providing Gulf War veterans with health-related information and receiving feedback on DoD health programs, DoD will engage active duty personnel, including senior enlisted personnel and officers, MCOS and VSOs, working with VA, in the process of information exchange within the next six months.

Also, in response to the PAC findings, DoD established a veterans outreach program designed to communicate information about Gulf War veterans' illnesses to veterans and local communities. The Office of the Special Assistant for Gulf War Illnesses communicates with MCOS and VSOs and feedback is received. In this manner, the MCOS and VSOs can participate in the dissemination of information regarding Gulf War Illnesses and ongoing efforts in providing care incident investigation, research and education. At the same time, the MCOS and VSOs are able to communicate to the outreach section the interests and concerns of the veterans making up their organizations.

One action taken by DoD was a demonstration and review of the type of chemical alarm and detectors used in the Gulf War. This demonstration, conducted on December 11, 1996 was well-received with representatives from nearly 20 organizations attending. Additionally, VSO workshops were conducted on January 30, and February 26, 1997. DoD will continue to host VSO workshops to stimulate a dialogue with veterans.

Findings and Recommendations Regarding Medical and Clinical Issues

Finding 2-10: DoD has not been responsive to the Committee's recommendation that prior to any deployment, DoD should undertake a thorough health evaluation, including a core set of diagnostics, of a large sample of troops to enable better post-deployment medical epidemiology along with timely postdeployment followup.

Recommendation: The PGVCB and other appropriate Departments and Agencies should be charged to develop a protocol to implement the following recommendation which was made in the Committee's *Interim Report*: Prior to any deployment, DoD should undertake a thorough health evaluation of a large sample of troops to enable better postdeployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services, including timely postdeployment followup.

Response: DoD concurs with this recommendation. Deployment medical surveillance programs are composed of three major components involving pre-deployment health screening and education, deployment operational, environmental, and medical surveillance, and post-deployment health surveillance and risk communication.

DoD strongly agrees with the importance of pre-deployment health assessment. The Department is developing a medical surveillance policy for deployments which specifies a uniform concept for health screening. Rather than targeting sample populations for assessment, the Department's position is that all deploying service members of specified deployments receive pre- and post-deployment screening to include standardized health screening questionnaires with medical follow-up as clinically indicated. This policy was partially implemented in Bosnia and is being fully implemented for Southwest Asia. We expect the new medical surveillance policy to be formally adopted during 1997.

VA and DoD have expertise relevant to this program area. Deployment medical surveillance planning and programs are of key importance to the success of future deployments and veterans health. The planning required overlaps the responsibilities of the CWG and RWG of the PGVCB. For these reasons, a fourth, newly constituted Deployment Planning Work Group will be formed by the PGVCB to make recommendations for appropriate action, coordinate interagency activities, and monitor these important programs.

Finding 2-11: FDA is moving toward soliciting public comment on alternatives to the Interim Final Rule related to permitting a waiver of informed consent for use of unapproved products during military exigencies. The Committee remains seriously concerned about the amount of time--currently exceeding six years--FDA is taking to open the process to public comment.

Recommendation: FDA should solicit timely public and expert comment on any rule that permits waiver of informed consent for use of investigational products in military exigencies. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long-term followup of individuals who receive investigational products; review by an institutional review board outside of DoD; and additional procedures to enhance understanding, oversight, and accountability.

Response: Concur. Since receiving the Committee's *Interim Report*, the Food and Drug Administration (FDA) has carefully evaluated the Committee's recommendations as well as other information that has come to its attention. FDA has engaged in discussions within the agency, with the DoD, and with others on this important topic. The issues that have been raised are complex and require extensive coordination. As a result of these discussions, the FDA is preparing regulations that will solicit public comment in line with the Committee's report. This public comment will be directed toward whether the FDA should finalize the Interim Final Rule, modify it, or eliminate it completely. As part of that process, FDA is exploring the approval mechanisms that should be applied to drug and biological products that may be used in military or civilian exigencies.

DoD agrees with the need for FDA to solicit timely public and expert comment on rules that permit waiver of informed consent for use of investigational products in military exigencies. DoD intends to work with FDA on ways to more expeditiously process such rules in order to ensure that we have effective countermeasures to deal with existing and new chemical and biological warfare threats. DoD agrees that, to the full extent feasible, there should be disclosure to service personnel, good record-keeping, and other procedures which enhance understanding, oversight and accountability. As one example, the long-term follow-up of individuals who receive investigational products such as pyridostigmine bromide (PB) will be enhanced by current research into the potential interaction of DEET, Permethrin and PB, which is being carried out at DoD laboratories as well as at the University of North Carolina and the University of Florida.

Finding 2-12: DoD has not been responsive to the Committee's recommendation that it should routinely inform recruits and troops, through orientation and training procedures, about the possible use of investigational drugs or vaccines for chemical and biological warfare agent proposed. DoD's lack of response in this highly sensitive area contributes to the perception of many that U.S. troops were inappropriately subjected to investigational drugs or vaccines during the Gulf War.

Recommendation: Given that FDA Interim Final Rule permitting a waiver of informed consent for use of unapproved products in a military exigency is still in

effect, DoD should develop enhanced orientation and training procedures to alert service personnel they may be required to take drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of chemical and biological warfare.

Response: Concur. Although medical personnel who participated in Operation Desert Storm were thoroughly briefed about the side effects of PB, this information did not, in most cases, get down to the individual service member. Some of the service members' concerns could have been alleviated had they known that the side effects they experienced were, in fact, attributed to the known side effects of PB, and which in most cases would go away as the service member became tolerant to those effects of PB. To address this issue, all new procurements, as well as existing stockpiles of PB, will contain appropriate labeling to inform the individual service member of potential side effects and provide warnings for use.

DoD already does some orientation and training for new troops on the chemical and biological threat and on the countermeasures which may be needed. More needs to be and will be done within the next twelve months. The goal of DoD is that every service member is fully informed during orientation and training of the health risks, benefits, and proper use of all medical countermeasures, and, that when used, such countermeasures are documented and maintained as a part of the individual's health record. Given the potential for serious chemical and biological threats for future conflicts, both using countermeasures and having our service members fully informed are critical to effectively protecting them. Our troop information program and the new DoD medical surveillance policy combine to enhance soldier welfare.

Given that FDA's Interim Final Rule permitting a waiver of informed consent for use of unapproved products in a military exigency is still in effect, DoD will develop enhanced orientation and training procedures to alert service personnel they may be required to take drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of chemical and biological warfare.

Finding 2-13: DoD has made progress in improving medical record keeping in-theater and stateside, but increased and sustained commitment from DoD's Joint Chiefs of Staff and Commanders in Chief will be necessary for current prototypes and plans to be fully and successfully integrated and implemented.

Recommendation: DoD officials at the highest levels, including the Joint Chiefs of Staff and the Commanders in Chief, should assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data (including classified information, if and when it is needed) in the field. DoD and VA should adopt standardized record keeping to ensure continuity.

Response: Concur. DoD continues to actively develop an automated medical records system that is used during deployments and when Service members are at their home base health facilities. Major portions of that system are already being used in Bosnia. Further refinements, including the addition of an automated patient record and "meditag" record, are being made as quickly as is feasible. These new information systems will be compatible with the records systems being used worldwide.

As part of a reengineering effort under a joint agreement between DoD and VA, the two agencies are working to ensure compatibility of DoD and VA systems and to facilitate the appropriate exchange of health information. VA and DoD jointly pursue resource sharing to promote continuity of health care between the two departments and reduce costs of services by avoiding the duplication of facilities, staff and equipment. To address automation sharing issues, the Chief Information Officer (CIO) of the Veterans Health Administration (VHA) established a Directorate for VA/DoD IRM (Information Resources Management) Sharing to provide a central point for the management of interagency agreements and the implementation of hardware and software to allow for non-VA workload in VHA's automation environment.

A variety of mechanisms are available to promote sharing between the agencies. The Federal Information Resources Sharing Work Group (FIRSWG) meets quarterly to discuss sharing issues concerning VA, DoD, and the Indian Health Service (IHS). DoD's Technical Integration Work Group (TIWG) encourages VA's participation in their monthly meetings to share technical policies, philosophies, and directions. Additionally, the VA-maintained Federal Health Care Resources Sharing (FHCRS) Database allows the VA/DoD Sharing Office to manage information about the more than four thousand sharing agreements between VHA and DoD facilities.

The VA/DoD IRM Sharing Directorate recently initiated the VA/DoD Data Exchange Project and is working with contractors to develop a national solution to the problem of sharing data between the two departments. The project's specific emphasis is on sharing laboratory data, and success in this area will significantly benefit VA and DoD health care providers. Inputs to this project include documentation and findings from related VA, DoD and commercial efforts. The I&I Laboratory will be used to develop and test the VA/DoD Data Exchange prototype.

The Pacific Medical Network (PACMEDNET) Project (now known as the Theater Medical Information Infrastructure (TMII) Project) demonstrated successful data sharing between Composite Health Care System (CHCS) and Veterans Health Information Systems Technology Architecture (VISTA) during the Cobra Gold exercises in Thailand in May 1996. The focus of the project is the use of a Transportable Computer-Based Patient Record (TCPR) to provide a comprehensive view of a patient's care history gathered from all medical facilities, DoD and VA, where a patient has received care. Following the success

of the Cobra Gold demonstration, the TMII Project was expanded to include facilities outside the Pacific geographical area.

The CWG of the PGVCB will actively encourage and monitor these interagency medical information systems efforts.

Recommendation: The PGVCB and other appropriate Departments and Agencies should be charged to develop a protocol to implement the following recommendation, which is made in the Committee's *Interim Report*. Prior to any deployment, DoD should undertake a thorough health evaluation of a large sample of troops to enable better post-deployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services, including timely post-deployment follow-up.

Response: Concur. As stated previously, DoD strongly agrees with the importance of pre- and post-deployment health assessment. The Department is developing a medical surveillance policy for deployments which specifies a uniform concept for health screening. Rather than targeting sample populations for assessment, the Department's position is that all deploying service members of specified deployments receive pre- and post-deployment screening to include standardized health screening questionnaires with medical follow-up as clinically indicated. This policy was partially implemented in Bosnia and is being fully implemented for Southwest Asia. Interim and final recommendations regarding deployment surveillance have been taken seriously by the PGVCB. DoD expects the new medical surveillance policy to be formally adopted during 1997. The newly established Deployment Surveillance Work Group will foster this activity.

Finding 2-14: Clinical staff not directly involved in VA's Registry and DoD's CCEP are not well informed about the programs.

Recommendation: VA and DoD should, in their educational outreach programs, specifically target staff members not directly involved in the care of Gulf War veterans.

Recommendation: DoD and VA should include timely updates on the CCEP or Persian Gulf Health Registry, respectively, in their Continuing Medical Education programs.

Recommendation: VA and DoD should regularly brief their staffs on the Gulf War research portfolio and on the results of research studies as they become available.

Response: Concur. VA and DoD recognize that Gulf War-related continuing medical education (CME) is an important component of assuring quality health care for Persian Gulf veterans and their families. Within the next twelve months,

VA and DoD will coordinate their departmental CME programs through the activities of the CWG.

VA has used a multifaceted approach to continuing medical education combining quarterly mailings of up-to-date scientific and clinical information, interactive conference calls, national satellite video-teleconferences, and on-site CME annual conferences. Future programs will continue to incorporate updates of clinical case series (Registry and CCEP) information, clinical findings in Coalition Forces, research developments and VA program updates.

In order to better address the needs of non-Persian Gulf Registry health care providers, VA has developed a print material CME self-study program which is scheduled for publication in the Spring of 1997. Copies of these materials will be made available to non-VA health care providers on request.

DoD has already begun to develop an information distribution plan concerning Gulf War veterans' illnesses through the three Service Surgeons General for health care providers within the Military Health Services System. DoD and VA will work together to expand the distribution of clinical and research information regarding Persian Gulf illnesses to all of their respective clinical staff through timely updates and CME programs.

Recommendation: VA and DoD should regularly review staffing needs, particularly in mental health, and increase recruitment and retention of adequate numbers of medical professionals to satisfy patient needs. Staffing reviews should consider that, despite increased medical surveillance and better preventive measures, future deployments also will generate a significant number of veterans who will need care for illnesses that are difficult to diagnose.

Response: Concur. DoD is reviewing the clinical staffing needs required to satisfy Gulf War veterans' health needs, including mental health, and ensuring that those staffing needs are met. With respect to future deployments, the Department has in place its CCEP, including support to all military treatment facilities, to assist with the evaluation and care of illnesses that may result from those deployments and are difficult to diagnose.

VHA's Prescription for Change made quality care, customer satisfaction and timely access to health-care services for eligible veterans a primary goal. Staffing requirements will be adjusted to meet these goals and reach the minimum performance measures set for primary care and consultations at VA Medical Centers. An established annual reporting of these performance measures will accomplish the "regular review" of staffing needs recommended by the Committee. VA and DoD have programs in place to deal with the expected number of difficult-to-diagnose illnesses resulting from future deployments.

The Departments are committed to provide quality health care and will take the Committee's staffing recommendation seriously.

Finding 2-15: Follow-up treatment, particularly when mental health visits are involved, is problematic within both VA and DoD. Staffing constraints occasion long delays in scheduling appointments. Commanders are sometimes resistant to making sufficient time off available for active duty veteran to maintain an adequate treatment program.

Recommendation: Since 1986, U.S. service members with certain chronic illnesses, e.g., asthma and diabetes, have been allowed to remain on active duty when regular medical monitoring is necessary. Veterans of the Gulf War with chronic illnesses are no different. Troop commanders should be reminded that adequate time off for follow-up medical appointments is a necessity and a priority.

Response: Concur. DoD will, within the next three months, develop an information distribution plan for Commanders concerning Gulf War veterans' illnesses. The Department will ensure that troop commanders are knowledgeable about the health needs of Gulf War veterans and are supportive when follow-up medical appointments are needed for Gulf War veterans with chronic illnesses.

Finding 2-16: Reproductive health care benefits available to active duty service members and their families through the Military Health Services System are comprehensive and the standard of care.

Finding 2-17: Reproductive health concerns are addressed on a case-by-case basis within DoD, and VA has extremely limited authority to treat such concerns at all. Neither DoD nor VA have widespread or systematic policies in place to address the concerns and questions of Gulf War veterans concerning reproductive health.

Recommendation: The government should conduct a thorough review of its policies concerning reproductive health and continue to seek statutory authority to treat veterans and their families for service-connected problems. When indicated, genetic counseling should be provided--either via VA treatment facilities or referral--to assist veterans and their families who have reproductive concerns stemming from military service.

Response: Concur. DoD provides reproductive health care for its service members and their families, and has made reproductive health concerns a higher priority for all beneficiaries in their reproductive years. Currently, the Department is putting into place performance matrices to better assess reproductive health outcomes and the associated health care and to assist in the overall management of that care. Special efforts are being made for Gulf War veterans in the areas of evaluation and care and epidemiological and other research.

VHA is conducting a review of reproductive health services offered to eligible veterans as part of its Eligibility Reform activities. Reproductive health services for Persian Gulf veterans will receive serious consideration as part of this program review.

Finding 2-18: DoD and VA have implemented innovative programs to help veterans cope with combat-related stress.

Recommendation: The government should continue and intensify its efforts to develop stress reduction programs for all troops, with special emphasis on deployed troops.

Response: Concur. DoD is currently writing a Directive which addresses the recognition and management of combat stress. When this policy directive is published, the Services will be expected to publish implementation instructions within 120 days. These instructions will focus on stress reduction programs, particularly for deployed troops. Meanwhile, special combat stress coping units have deployed to Bosnia and conduct critical incident stress debriefings for catastrophic incidents that occur in the Services.

VA, DoD and DHHS will work together through the PGVCB CWG to monitor and enhance the Departmental programs.

Recommendation: Since leadership and unit cohesion are so important in managing stress, DoD should specifically involve senior commanders and senior noncommissioned officers in stress management programs.

Response: Concur. DoD, through the forthcoming Directive on Combat Stress (discussed above), will set the policy to have senior commanders and non-commissioned officers involved in stress management programs.

Findings and Recommendations Regarding Research

Finding 2-19: DoD and VA have not taken serious steps to encourage their principal investigators to convene and use public advisory committees for its Gulf War veteran's epidemiologic health research.

Recommendation: The RWG of the PGVCB should require that any proposals for new, large-scale Gulf War veterans' epidemiologic health research describe a plan to incorporate a public advisory committee into the study design, dissemination of results, or both. The RWG should consider justifying a waiver of such a committee under rare circumstances.

Response: Concur. Principal Investigators (PIs) conducting large epidemiologic studies have been encouraged to establish Public Advisory Committees. Future Requests for Proposals will require PIs to incorporate Public Advisory Committees into the study design and results dissemination phases of the research.

The RWG of the PGVCB agrees with the Committee recommendation that any proposals for new, large-scale Gulf War veterans' epidemiological studies of Persian Gulf veterans incorporate a Public Advisory Committee. In the December 19, 1996 teleconference of the RWG, the members unanimously agreed to make funding of future large-scale epidemiological studies contingent on the appointment of a public advisory committee. The RWG has also recommended that ongoing epidemiological studies institute Public Advisory Committees. This recommendation has been transmitted to the relevant PIs.

Finding 2-20: DoD's Persian Gulf Registry of Unit Locations lacks the precision and detail necessary to be an effective tool for the investigation of exposure incidents. The effort has been no more successful than the effort to compile similar information following the Vietnam War to examine possible exposures to Agent Orange.

Recommendation: The government should develop more accurate methods of recording troop locations to facilitate post-conflict health research in the future. DoD should make full use of global positioning technologies.

Response: Concur. The PAC is correct in pointing out that the Persian Gulf Registry of Unit Locations database lacks the precision to serve as the basis for determining individual locations for investigation of exposure incidents. Individuals do not remain with their units throughout a conflict but rather deploy in small groupings or as individuals. Combat, Combat Service and Combat Service Support soldiers frequently are called upon to cross march or work in small teams on a temporary basis to satisfy mission requirements, e.g. fuel handlers regularly make 50 kilometer round trips to refuel front line units.

Individual and team movements are too numerous to track in detail in unit level daily journals. Although it cannot be considered to be a singularly authoritative source of information, the Joint Services Environmental /support group database does provide decision makers with a valuable tool for the investigation of unit movements in the gulf War. It should not and can not be used as the exclusive source for investigation of exposure incidents. The recommendation that DoD make full use of global positioning technologies is sound and this technology is being tested and incorporated throughout the Services. The efficacy of global positioning technologies to track individual and unit situational awareness will be demonstrated by the Army and other Services during the March 1997 Task Force XXI Advanced Warfighting Exercise at the National Training Center, Fort Irwin, California.

Finding 2-21: Overall, the government's current research portfolio on Gulf War veteran's illnesses is appropriately weighted toward epidemiologic studies and studies on stress-related disorders that are more likely to improve our understanding of Gulf War veterans' illnesses. For the most part, the government prioritization process has worked.

Finding 2-22: Research on Gulf War veteran's illnesses is treated, appropriately, as a subset of the government's broader research portfolio on the health consequences of military service. Any new research should be directed toward the principal uncertainties, which are: long-term health effects from stress; long-term health effects from low-level exposure to chemical weapons; long-term health effects from exposure to known carcinogenic and mutagenic compounds, such as mustard agent; and long-term health effects of interactions between pyridostigmine bromide and other agents.

Finding 2-23: Stress is not well understood in terms of diagnoses, physiological sequelae, and effective prevention and treatment strategies; yet it is likely to be an important contributing factor to illnesses currently reported by Gulf War veterans. Additional attention to basic and applied research on stress-related disorders across the entire federally funded biomedical research portfolio would benefit DoD's and VA's capabilities to manage combat stress and its effects.

Recommendation: The government should plan for further research on possible long-term health effects of low-level exposure to organophosphorus agents such as sarin, soman, or various pesticides, based on studies of groups with well-characterized exposures, including: a) cases of U.S. workers exposed to organophosphorus pesticides; and b) civilians exposed to the chemical warfare agent sarin during the 1994 and 1995 terrorist attacks in Japan. Additional work should include followup and evaluation of an appropriate subset of any U.S. service personnel who are presumed to be exposed during the Gulf War.

The government should begin by consulting with appropriate experts, both governmental and nongovernmental, on organophosphorus nerve agent effects. Studies of human populations with well-characterized exposures will be much more revealing than studies based on animal models, which should be given lower priority.

Response: Concur. The recommendation for more research on low-level exposure to organophosphorus agents is fully supported by the PGVCB. In December 1996, the RWG has released the 1996 revision of *A Working Plan for Research on Persian Gulf Veterans' Illnesses (Working Plan)* first published in 1995. The RWG developed the revision as a part of its ongoing commitment to continually reevaluate the research needs for Persian Gulf veterans' illnesses. In the 1996 *Working Plan*, the RWG developed focused research recommendations based on the current state of information and understanding regarding the nature and potential causes of Persian Gulf veterans' illnesses. Near-term recommendations for additional research include:

- Follow-up of the mortality experience of Persian Gulf veterans, encompassing cause-specific mortality, at appropriate future time-points;
- More longitudinal follow-up studies of the health of Persian Gulf veterans, including those with illnesses that are difficult to diagnose;
- Critical peer-review of models used to predict exposure concentrations of environmental pollution (such as the Kuwait oil well fires) and chemical warfare agents (such as the demolition of weapons storage sites at Khamisiyah in March 1991 and aerial bombing of chemical weapons facilities during the air war);
- Assessment of the potential for clinical investigations of the health status of the service members in the vicinity of Khamisiyah when weapons bunker 73 and the storage pit were detonated in March 1991. If deemed possible, such clinical investigations should be carried out;
- Additional research on health-related issues arising from the Persian Gulf experience but with potential for more general applicability to future conflicts is also recommended, including:
 - ◊ Investigation of the risk factors for the development of stress-related disorders including, but not limited to, post-traumatic stress disorder (PTSD);
 - ◊ Exploration of the development of practical, sensitive, and specific biomarkers of exposure to chemical agents, including organophosphate nerve agents and vesicants such as sulfur mustard;
 - ◊ Toxicological and, where feasible, epidemiological research on the potential for long-term health effects resulting from low-level, sub-clinical exposures to chemical agents, particularly organophosphate agents such as sarin;
 - ◊ Development of a strategic plan for research into the potential long-term health consequences of exposure to low-levels of chemical warfare agents; and,

- ◊ If a simple, sensitive and specific, as well as economic, test for *L. tropica* infection becomes available, seroepidemiologic studies may be undertaken in Persian Gulf veterans. Indeed, when feasible and practical, sera of veterans should be stored in expectation of the possibility for such studies. Despite the declining importance of *L. tropica* as a risk factor in Persian Gulf veterans, continued research on tests for *L. tropica* infection is valuable for potential future deployments.

In addition to a study of the feasibility of conducting epidemiological investigations of the health of veterans present at Khamisiyah in March 1991, the RWG is explicitly recommending more research on the potential toxic effects of low-level chemical warfare agents. A Broad Agency Announcement from DoD in December 1996 solicits applications to conduct the aforementioned feasibility study, and it solicits applications for toxicological research on the toxic effects of low-level chemical warfare agent exposure. DoD is asking the scientific community to help us determine what mix of human population and animal model studies will provide the best understanding of this complex issue. The RWG agrees that population studies of low-level chemical weapons exposure should consider a variety of exposed populations including U.S. pesticide workers, civilians exposed to sarin in Japan during terrorist attacks in 1994 and 1995, as well as appropriate subsets of Persian Gulf veterans who may have been exposed during the Persian Gulf War. Investigators with the VA are collaborating with Japanese scientists on studies of the health of victims of the Tokyo subway incident in 1995.

The RWG also agrees that it should broaden its expertise base for consultations on the health effects of nerve agents. As part of an effort to do this, the RWG sponsored a Symposium on the Health Effects of Low-Level Exposure to Chemical Warfare Nerve Agents as a part of the Annual Meeting of the prestigious Society of Toxicology held on March 7 and 8, 1997. In the coming months the RWG will be developing a comprehensive research strategy for studies of the toxic effects of low-level exposures to chemical warfare agents. This strategy will be developed using input from appropriate government and non-government experts.

Recommendation: Since a number of Gulf War risk factors are potential human carcinogens that could result in increased rates of cancer beginning decades after exposure, VA should continue to monitor Gulf War veterans through its ongoing mortality study for increased rates of lung, liver, and other cancers.

Response: Concur. VA's Environmental Epidemiology Service is studying mortality rates and cause-specific mortality among Gulf War veterans through December 1995. VA plans to support periodic updates and long-term mortality studies on deployed and non-deployed Gulf era veterans.

Recommendation: Depleted uranium munitions are likely to be used in future conflicts involving U.S. service personnel. To fully elucidate the health effects of depleted uranium munitions, VA should conduct research that compares the health status of individuals with embedded fragments of DU shrapnel with appropriate control groups.

Response: Concur. The depleted uranium health surveillance program is located at the Baltimore VAMC. VA recognizes the importance of research and health surveillance activities which will improve our knowledge of the potential health effects of human exposure to depleted uranium. VA is committed to long-term monitoring of the health of the Army veterans with retained depleted uranium fragments. Furthermore, the RWG of the PGVCB will monitor and foster the research which is ongoing within the U.S. Army and VA.

Recommendation: The government should continue to collect and archive serum samples for U.S. service personnel when feasible.

Response: Concur. Currently, DoD is finalizing a medical surveillance policy which will require serum collection for specified deployments. This policy will be in place during 1997. The RWG recommends that when feasible, all research studies should collect and archive serum samples.

Finding 2-24: The efforts of the PGVCB's RWG would benefit from the active participation of additional representatives from other federal agencies with relevant expertise, such as the National Institutes of Health and the Agency for Toxic Substances and Disease Registry.

Recommendation: The RWG should more thoroughly consult with other federal agencies with relevant expertise--such as the National Institutes of Health (NIH) (particularly the National Institute of Environmental Health Sciences) and the Agency for Toxic Substances and Disease Registry--on basic, clinical, and epidemiologic research and on risk communication.

Response: Concur. The PGVCB will work with the other members of the RWG to obtain the active participation of appropriate expert representatives from NIH and ATSDR as well as experts from other agencies within the next three months. The RWG's current membership includes the following Departments and Agencies:

Department of Veterans Affairs
Office of Research and Development

Office of Public Health and Environmental Hazards

Department of Defense

Office of the Assistant Secretary for Health Affairs
Office of Defense Research and Engineering
Division of Environmental and Life Sciences

Department of Health and Human Services

Office of Public Health and Science
Centers for Disease Control and Prevention
Agency for Toxic Substances and Disease Registry
National Institutes of Health
National Institute of Environmental Health Sciences

Environmental Protection Agency

National Center for Environmental Assessment

These members will be supplemented by a broader membership with the expertise from a wider range of government agencies.

Finding 2-25: VA's November 1996 establishment of a new Environmental Hazards Center focused on reproductive health and developmental outcomes from environmental exposures is an important step forward in developing policies for the treatment of veterans and addressing their concerns.

Response: Concur. With the increasing number of women veterans, VA recognizes the growing need to understand the potential consequences of military service on reproductive health and outcomes in both men and women. VA research historically has not focused on these areas. However, in the Spring of 1996, VA issued a solicitation for a fourth Environmental Hazards Research Center focusing on potential reproductive and developmental outcomes associated with toxic exposures during military service. After a comprehensive and competitive scientific peer review, VA announced in November 1996 the award of this new Environmental Hazards Research Center to the Louisville, VA Medical Center in collaboration with the University of Louisville. The new Center is an important step to enhance VA's research efforts in these important research areas.

Findings and Recommendations Regarding Chemical and Biological Weapons

Finding 2-26: In the face of credible evidence of the presence or release of chemical warfare agents, low-level exposure of U.S. personnel at the affected site must be presumed while efforts to develop more precise measures of exposure continue.

Finding 2-27: The evidence of chemical warfare agent release at Khamisiyah is overwhelming, and low-level exposure to troops within a 50 kilometer radius should be presumed while efforts to develop more precise measures of exposure and more detailed knowledge of the demolition activities continue.

Recommendation: All U.S. service personnel assigned to units near the Khamisiyah demolition activity should be notified and encouraged to enroll in VA's Persian Gulf Health Registry or DoD's Comprehensive Clinical Evaluation Program. In determining the extent of possible chemical warfare agent exposure at Khamisiyah and any other sites that future investigations uncover, the government should use the best theoretical and practical assessment tools available. The Committee recognizes the large number of variables that can affect the outcome of any determination, but identifies the following as essential principles:

- Where objective, un rebutted evidence suggests the release of chemical warfare agents in the vicinity of U.S. troops, every effort should be made to identify the source of the agent and to model the downwind footprint of the potential distribution of agent at the general population exposure level (or lower threshold, if appropriate);
- When a downwind footprint is established, a conservative, presumptive-exposure area should be defined that reflects the uncertainties of the modeling effort. The presumptive-exposure area should, at a minimum, include all sites within a circle that has a radius equal to the length of the downwind footprint; and
- Troops within the presumptive-exposure area should be notified and encouraged to enroll in the CCEP or Registry.

Response: Concur. DoD initiated a notification program in August 1996 for all service members assigned to units thought to have participated in the operation at Khamisiyah. The total number of individuals assigned to these units, and therefore included in this notification program, totaled 1,168. This telephone outreach program informed service members assigned to these selected units of the incident and of the medical evaluation programs available to them through VA and DoD.

During this period, the Central Intelligence Agency (CIA) attempted to model the conditions at Khamisiyah in order to estimate the dispersion of any chemical agents. Preliminary information from the model indicated exposures which could produce immediate health effects, may have occurred as far as 25 km from Khamisiyah on the date of the "pit" demolition, March 10, 1991. To cover

the dates surrounding the bunker and “pit” demolitions and to build a larger margin for error, the notification program expanded to include service members attached to any unit within a 50 kilometer radius of Khamisiyah at any time on or between the dates of March 1-15, 1991. These parameters were considered conservative enough to absorb any possible variation in the geographic and temporal distribution of chemical agents modeled by the CIA. This action increased the number of veterans to be notified to 20,867. A letter was mailed notifying the involved individuals of the incident and encouraging them to participate in the medical evaluation programs available to them through the VA or DoD. In addition, a survey to gather information to better understand the events surrounding the Khamisiyah demolition and Gulf War illnesses has been mailed to all affected individuals.

In order to better understand any relationship between the demolitions, potential exposure and subsequent illness, DoD and VA are sponsoring epidemiological studies and funding research.

For any other sites that may be identified in the future and for any other service members who may have been exposed, similar steps will be taken with respect to notification, evaluation, care and research.

Finding 2-28: Other site-specific exposures of U.S. Troops to low levels of chemical warfare agents cannot be ruled out. A theater-wide time/distance analysis is insufficient to address positive detections by Fox reconnaissance vehicles and M256 kits.

Recommendation: All reports of positive M256 kits and Fox detections must be thoroughly investigated. Where unit logs record positive detections by either type of equipment, members of that unit should be notified and encouraged to enroll in VA’s Persian Gulf Health Registry or DoD’s Comprehensive Clinical Evaluation Program.

Response: Concur. All confirmed positive detections that meet the standard of Recommendation 2-27 will be thoroughly investigated. DoD will examine records to encourage all veterans of units in the vicinity of these detections to enroll in the VA’s Persian Gulf Health Registry or DoD’s Comprehensive Clinical Evaluation program as was done for the Khamisiyah incident. The current list of possible detections should not be taken as definitive. DoD intends to apply the PAC’s standard stated in Recommendation 2-27 and adopt a conservative and cautious approach with regard to possible detections. DoD’s improved veterans outreach program may uncover additional information of possible detections. Each reported detection will be investigated. In order to better understand any relationship between the demolitions, potential exposure and subsequent illness, DoD and VA will sponsor appropriate epidemiological studies and research.

DoD's Office of the Special Assistant has established a new case-management structure to ensure a thorough and complete investigation of all events surrounding a case. Reported detections are only one piece in the analytical process surrounding a particular incident.

The PGVCB will incorporate this knowledge into its activities including clinical care, research and risk communication.

Finding 2-29: DoD has conducted a superficial investigation of possible chemical warfare agent exposures, that is unlikely to provide credible answers to veterans' questions.

Recommendation: To ensure credibility and thoroughness, further investigation of possible chemical or biological warfare agent exposures during the Gulf War should be conducted by a group independent of DoD. Openness in oversight activities -- including public access to information and veteran participation -- public notice of meetings, opportunity for public comment, and regular reporting are essential. Full public accountability is critical.

Response: Concur in part. Consistent with the principle of independent oversight, on January 30, 1997, the President signed Executive Order 13034 extending the Presidential Advisory Committee on Gulf War Veterans' Illnesses. The Executive Order directed the Committee to provide "oversight of the ongoing investigation being conducted by the Department of Defense with the assistance, as appropriate, of other executive departments and agencies, into possible chemical or biological warfare agent exposure during the Gulf War." The Committee was also assigned the role of evaluating the Federal government's plan for and progress towards the implementation of all of the Committee's recommendations set forth in its Final Report. Finally, the Executive Order established two milestones for the Committee with respect to providing advice and recommendations related to its two principal roles: an interim status report by April 30, 1997; and a final supplemental report by October 31, 1997.

DoD is fully committed to a comprehensive and credible investigation of Gulf War veterans' illnesses, and has pledged a thorough investigation and will share the results of that investigation with our veterans and the American people. DoD is committed to ensuring a successful resolution of this issue for those Gulf veterans who served as well as those who will serve in future operations. DoD is morally obligated to provide our veterans an explanation that maintains the confidence of the force and the support of parents whose sons and daughters wear the uniform of our country. The expertise and knowledge to investigate, analyze and to understand what happened resides in the Pentagon.

DoD welcomes oversight and is committed to openness, communication and truthfulness. As indicated, the Office of the Special Assistant has an office for a PAC representative within our complex and will make available, as necessary, space for other oversight activities.

Committee Findings and Recommendations Regarding Coordination

Finding 2-30: Many issues related to post-conflict health concerns of Gulf War veterans are common to the aftermath of other military engagements. Governmental responsibility to address such concerns spans the missions of several federal departments and agencies, but it is a priority for no agency. Resolving these issues in a timely and effective manner requires interagency coordination at the highest levels of government.

Recommendation: A Presidential Review Directive (PRD) should be issued to instruct the National Science and Technology Council to develop an interagency plan to address health preparedness for and readjustment of veterans and families after future conflicts and peacekeeping missions. The President's Committee of Advisors on Science and Technology and other nongovernmental experts, as appropriate, should be asked to review the plan 12 months after the PRD is issued and again at 18 months to ensure national expertise is brought to bear on these issues.

Response: Concur. VA, DoD and DHHS support a Presidential Review Directive (PRD) process to address the many post-deployment health concerns highlighted by the Gulf War experience including the conduct of relevant research efforts. A draft PRD, entitled "Development of Interagency Plans to Address Health Preparedness for and Readjustment of Veterans and their Families After Future Deployments," has been drafted by the Office of Science and Technology Policy in the White House. That draft is currently circulating for final interagency clearance; it is anticipated that the clearance process will be completed by the end of March 1997.

Once the directive responding to the PAC's recommendation is approved, the relevant agencies will be asked to review policies and programs and identify relevant actions that may be taken by the Federal government to better safeguard those individuals who risk their lives and well-being on deployments to defend our Nation's interests. The PRD will be specifically addressed to the following officials: the Vice President; the Secretaries of Defense, Health and Human Services, and Veterans Affairs; the Director of the Office of Management and Budget; the Assistant to the President for National Security; and the Assistant to the President for Science and Technology. If the PRD process within a given agency generates recommendations to support higher priority budgets, programs or policies, then the responsible official must include in the agency report a specific

strategy on how these recommendations can be accommodated within and among the balance of the agency's budget priorities.

All of the agency-specific inputs with respect to the issues identified by the PAC will be integrated into a comprehensive report by the National Sciences and Technology Council (NSTC) within one year after the issuance of the PRD. The President's Committee of Advisors on Science and Technology (PCAST) will provide input for the report review process, then take cognizance of the report for final review and approval.

CHAPTER 3: NATURE OF GULF WAR VETERAN'S ILLNESSES

Finding 3-1: Gulf War veterans have experienced no excess mortality from natural causes during or after the war. Gulf War veterans have experienced excess mortality from external causes such as injuries, which is consistent with the experience of veteran populations from previous conflicts.

Recommendation: Research on possible causes and methods of prevention of excess mortality from external causes among veterans should receive high priority.

Response: Concur. Long-term mortality follow-up studies concerning external causes are important to determine the cause of excess rates among deployed troops compared to other troops. As a result, DoD and DHHS will collaborate with VA investigators to conduct these long-term mortality studies with the goal to identify risk factors and develop appropriate interventions.

The mortality study carried out by VA's Environmental Epidemiology Service found that Gulf War veterans experienced a small, but significant increased death rate as compared to non-deployed Gulf era veterans. However, this increased risk was almost entirely accounted for on the basis of external causes, such as automobile accidents. There was no difference in death rates due to medical conditions and Gulf War and non-deployed Gulf era veterans had almost half the mortality rate of the general U.S. population.

This increased risk of accidental death was also seen in Vietnam veterans. VA's Environmental Epidemiology Service has already begun a feasibility study of mortality due to external causes. In addition, VA's Environmental Epidemiology Service is completing an extension of the mortality study results through December 1995. PGVCB made research in this area a priority in its recently published 1996 update of the *Working Plan* and is committed to continuing this work.

Finding 3-2: Information from the clinical programs indicates musculoskeletal conditions and ill-defined conditions are common components of Gulf War veterans' illnesses.

Recommendation: Research on Gulf War veterans' illnesses should emphasize investigating the causes and methods of prevention and treatment of musculoskeletal conditions.

Response: Concur. Musculoskeletal disorders have been an important source of morbidity in all veteran populations, including the Persian Gulf War. As a part of their broader research agendas, both VA and DoD have significant resources devoted to musculoskeletal disorder research.

The PGVCB agrees that research on causes and methods of prevention and treatment of musculoskeletal conditions is an important area for investigation. In funding future research, VA and DoD will look for opportunities that would increase understanding of causes, prevention and treatment of these health problems.

Finding 3-3: Data from the clinical programs and epidemiologic studies indicate stress-related disorders are common components of Gulf War veterans' illnesses.

Recommendation: Research on Gulf War veterans' illnesses should emphasize investigating the causes and the methods of prevention and treatment of stress-related disorders.

Response: Concur. Traumatic and non-traumatic stress-related disorders may be an important contributing factor to Gulf War veterans' illnesses. Research will be solicited which investigates the possible association of traumatic and non-traumatic stress and Gulf War veterans' illnesses. We agree that research on causes and methods of prevention and treatment of stress-related disorders is an important area for investigation. In funding future research, the government will look for opportunities which would increase understanding of causes, prevention and treatment of these health problems.

Finding 3-5: Stigmatization of psychosomatic illness seriously interferes with some veterans seeking care.

Recommendation: Since the stigmatization of mental illness continues to be a problem for society at large, DHHS should place a priority on developing public education outreach programs that note the indissoluble association between the mind and the body. DoD and VA should make a special effort to address and target such needed educational outreach to their communities.

Response: Concur. DHHS believes that there unfortunately continues to be societal-wide stigmatization of those with mental illnesses. DHHS, principally through the National Institute of Mental Health and the Substance Abuse and Mental Health Services Administration, has been working diligently for several decades to improve the awareness of all Americans about the nature of mental health. Significant strides have been made since 1990 when DHHS launched its "Decade of the Brain" theme, providing a focus not only on neuroscience, but on improving public awareness and understanding of a broad range of diseases, including psychosomatic and stress induced conditions. Much of the integrative efforts of the program are directed toward

making precisely the mind-body linkage recommended in the Committee's report.

To heighten awareness of the nature of mental health, improve the public's understanding of these illnesses, and bring focus to the legitimacy and treatability of psychological conditions, DHHS has taken the initial steps to commission a Surgeon General's Report on Mental Health. DHHS believes that this report, along with its ongoing educational efforts, will positively impact how society approaches issues of mental health and stress-associated problems. DHHS is fully supportive of the Committee's recommendation.

DoD concurs with this recommendation and sees the release of the DoD Directive on combat stress in 1997 as a landmark directive, the first that the Department will have published on combat stress. The integration of psychological assessment into the overall physical assessment for pre-deployment examinations should help to destigmatize the psychophysiology processes. In addition, a Directive on Mental Health Assessment should help to further destigmatize the use of mental health services. The publication of these directives will be further enhanced by educational outreach efforts suggested above.

VA, DoD, and DHHS will incorporate this issue into the 1997 comprehensive risk communication plan.

Finding 3-4: Among the subset of the Gulf War veteran population examined in the ongoing clinical and research programs, many veterans have illnesses likely to be connected to their service in the Gulf. Currently, the extent of service-connected illness in the population is unknown.

Finding 3-6: It is unlikely that exposures in the Gulf War theater are responsible for the birth defects of children born to veterans.

Finding 3-7: VA's examination program for spouses and children of Gulf War veterans has little or no value as a research program and offers no incentive for participation, thus raising expectations about the government's ability to respond to health care needs in veterans and their families that are impossible to meet.

Recommendation: Since Congress has extended VA's examination program for spouses and children of Gulf War veterans, VA should formulate what it intends to do with the results and consider mechanisms to reimburse travel and other costs.

Response: Concur in part. Section 107 of PL 103-446 did not grant VA general authority to treat or provide medical care to the spouses and children of Persian Gulf veterans. In addition the study conducted under this section can only render

data of limited scientific value, because of the inherent limitations of the required study design. More specifically, under section 107 of Public Law 103-446, VA medical evaluations can be offered to any individual who:

- is the spouse or child of a veteran, who (a) is listed in the Persian Gulf War Veterans Registry established under Public Law 102-585, and (b) is suffering from an illness or disorder;
- is suffering from, or may have suffered from, an illness or disorder (including a birth defect, miscarriage, or stillbirth) which cannot be dissociated from the veteran's service in the Southwest Asia theater of operations; and
- has granted VA permission to include in the Registry relevant medical data from the evaluation.

Given the limited authority provided by this law, VA established a program that provides standardized medical evaluations and establishes a Registry database for health surveillance. The Department plans to analyze this database in a manner comparable to the VA Persian Gulf Registry database and the DoD CCEP database. This analysis will maximize our ability to compare the examination results of PGW veterans' spouses and children with the existing VA and DoD Persian Gulf health registries.

In the absence of authority to reimburse travel costs for participants in this program, VA is exploring means to reduce this burden and increase access to the program. In January 1997, VA increased the participating examination centers to 33 sites nationwide and is encouraging VHA Network Directors to add additional sites.

It should also be noted that VA's National Persian Gulf Veterans Health Survey is studying the health status of Persian Gulf veterans, their spouses and children, and VA will be providing physical examinations of veterans and family members during Phase III of this study. This randomized, controlled study will allow VA to assess the health status of Persian Gulf veterans and their families in a scientifically valid manner.

Finding 3-8: The absence of baseline data regarding the reproductive history and health of military personnel makes determinations of the effects of exposures during deployments more complex and difficult.

Recommendation: The government should consider methods for routinely sampling military populations regarding reproductive health so that an appropriate baseline exists for evaluating reproductive outcomes following deployment. In particular, DoD should consult with the National Center for Health Statistics and strongly consider implementing its National Survey of Family Growth and related methodologies for collecting data.

Response: DoD agrees and is considering several options to establish appropriate reproductive outcome baseline data including survey instruments, adverse birth outcomes registries and other reproductive outcomes surveillance systems. As

part of these deliberations over the next twelve months, DoD will be consulting with a number of outside organizations, including the National Center for Health Statistics.

CHAPTER 4: SCIENTIFIC ANALYSIS OF GULF WAR RISK FACTORS

Finding 4-1: Although some veterans clearly have service-connected illnesses, current scientific evidence does not support a causal link between the symptoms and illnesses reported today by Gulf War and exposures while in the Gulf region to the following environmental risk factors assessed by the Committee: pesticides, chemical warfare agents, biological warfare agents, vaccines, pyridostigmine bromide, infectious diseases, depleted uranium, oil-well fires and smoke, and petroleum products. Some of these risk factors explain specific, diagnosed illness in a few Gulf War veterans, for example, leishmaniasis has been diagnosed in 32 individuals. Prudence requires further investigation of some areas of uncertainty, such as the long-term effects of low-level exposure to chemical warfare agents and the synergistic effects of exposure to pyridostigmine bromide and other risk factors.

Response: Concur. Prudence dictates a continued investigation of all potential risk factors in which scientific evidence does not clearly indicate that health effects in Persian Gulf veterans are unlikely. Furthermore, the PGVCB recognizes that findings from these investigations will have relevance to the health consequences of future military deployments and to the health of the civilian community as well. Therefore, the RWG believes that a broad based research agenda is prudent, warranted, and ultimately beneficial to both military service members and civilians.

Finding 4-2: A number of Gulf War risk factors -- e.g., mustard gas, aflatoxin, and certain petroleum products--are potential human carcinogens that could cause increased rates of cancer beginning decades after exposure.

Recommendation: DoD and VA should perform long-term mortality studies of Gulf War veterans appropriate for investigating cancer rates in the Gulf War veteran population in the coming decades.

Response: Concur. Long-term mortality follow-up studies are important and should be funded to determine cancer rates among deployed troops compared to other troops.

Currently, VA's Environmental Epidemiology Service is collecting information on the mortality experience and cause-specific mortality among Gulf War veterans through December 1995. In the future, VA plans periodic updates and long-term mortality study on deployed and non-deployed Gulf era veterans.

Finding 4-3: Stress is known to affect the brain, immune system, cardiovascular system, and various hormonal responses. Stress manifests in diverse ways, and is

likely to be an important contributing factor to the broad range of physiological and psychological illnesses currently being reported by Gulf War veterans.

Recommendation: The entire federal research portfolio should place greater emphasis on basic and applied research on the physiologic effects of stress-related disorders.

Response: Concur. Stress may be an important, but not the exclusive, risk factor for Gulf War veteran's illnesses. The PGVCB agrees on the need for a greater emphasis on physiologic effects of both traumatic and nontraumatic stress in its research plan. This issue was incorporated into the December 1996 update of the *Working Plan*. In proceeding, the first step is to examine the research that is already being conducted, learn from that research and identify gaps in research knowledge. The PGVCB agrees about the need for a better understanding of the relationship between exposure to both traumatic and nontraumatic stress and its role in physical and psychological illnesses. In PTSD research alone, VA has invested nearly \$7 million and VA investigations have received another \$4.5 million from non-VA sources, such as NIH. VA and DoD are partnering in an effort to expand their resource portfolios on stress-related research through the DoD/VA cooperative research program. It will be very important to compile the ongoing and past research that is relevant to stress disorders in the format used by the PGVCB: methods, completion date, findings. This would allow a current review of areas that have and have not been addressed and an opportunity to better use current research knowledge, as well as help determine future research priorities.

DoD, through the PGVCB, is actively participating in the process for finding and selecting the best scientific proposals for funding involving the health outcomes associated with stress. Two efforts are underway: proposals are being sought by a formal Request for Proposals for researchers external to the federal government as well as through via the VA intramural system.

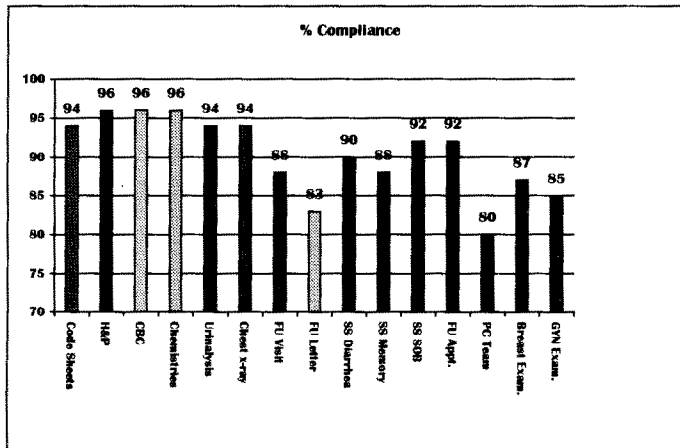
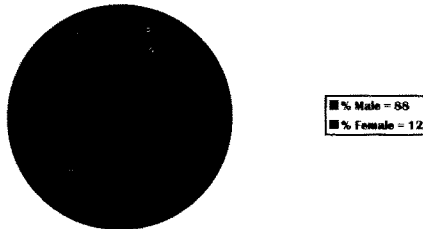
ATTACHMENT B
(THE HONORABLE LANE EVANS)

Persian Gulf Registry Health Examination Program
Quality Management/Self Assessment Monitor

Background/Purpose: VHA Directive 10-95-114 required each VA medical center to use the Persian Gulf Registry Health Examination Program - Quality Management/Self Assessment Monitor to review at least a 10% sample of all Persian Gulf Registry physical examinations conducted from January 1, 1996 through September 30, 1996.

Facilities recorded the results of their medical record reviews on Attachment B, Summary Analysis of Self Assessment Monitor Results, and submitted them to Environmental Agents Service (EAS). The information shown below represents a summary analysis of results submitted to EAS by 167 VA facilities during the 1996 monitoring period.

SUMMARY ANALYSIS OF SELF ASSESSMENT MONITOR RESULTS
JANUARY 1, 1996 ⇒ SEPTEMBER 30, 1996



Year-to-Year Percentage Compliance Comparison

	⇒1995	1996		⇒1995	1996
Code Sheets	93%	94%	SS Diarrhea	88%	90%
H&P	94%	96%	SS Memory	84%	88%
CBC	94%	96%	SS SOB	89%	92%
Chemistries	95%	96%	FU Appt.	88%	92%
Urinalysis	95%	94%	PC Team	70%	80%
Chest x-ray	92%	94%	Breast Exam.	76%	87%
FU Visit	82%	88%	GYN Exam.	70%	85%
FU Letter	81%	83%			

**Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420**

ATTACHMENT C
(THE HONORABLE LANE EVANS)
VHA DIRECTIVE 97-008

February 19, 1997

VHA'S SERVICE EVALUATION AND ACTION TEAM

1. PURPOSE: The purpose of this Veterans Health Administration (VHA) Directive is to establish a Service Evaluation and Action Team (SEAT) within each Veterans Integrated Service Network (VISN) office to enhance VHA's responsiveness to patient needs and service satisfaction. The SEAT will provide a mechanism for each VISN office to continually assess opportunities to enhance the effectiveness of Department of Veterans Affairs (VA) clinical programs and to respond to veterans' concerns. The SEAT enables all medical center Directors, VISN Directors, and VHA Headquarters' program staff to track trends in customer concerns and complaints and to conduct a self-assessment on a periodic basis. The initial SEATs will be piloted with Persian Gulf Veterans Programs and, if successful, expanded to other program areas in the future.

2. POLICY: All VISN Offices will implement a SEAT not later than March 1, 1997.

3. ACTION

a. Each VISN director will appoint the members of the Network SEAT. Membership shall include, but is not necessarily limited to, the following:

- (1) The VISN Clinical manager, who will serve as Chairperson of the SEAT;
- (2) A veterans service organization representative;
- (3) A VA medical center Chief of Staff;
- (4) A VA medical center patient representative and/or advocate;
- (5) A Persian Gulf Registry physician;
- (6) A Vet Center representative;
- (7) A quality improvement manager; and
- (8) A regional veterans benefits counselor.

b. The SEATs will listen to and monitor trends in veterans' (individual or group) concerns about health care access, appropriateness, quality and fulfillment of VA program mandates within the VISN or at its medical facilities. The information gathered on reported concerns and recommendations for favorable resolution will be referred to local medical facility staff for action. The SEAT will monitor such action and results. The goal of each SEAT referral is to improve communication with veterans, their families, and other stakeholders, where possible, to improve the responsiveness of VA health care delivery.

THIS VHA DIRECTIVE EXPIRES JANUARY 30, 1998

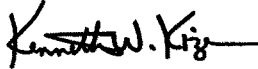
VHA DIRECTIVE 97-008
February 19, 1997

c. Requests and referrals to the SEAT for action can be made by veterans, veterans service organizations, VA hotline staff, veterans benefits counselors, VA regional offices and others. The SEAT will also receive input from national and local customer satisfaction and quality improvement programs.

d. SEAT referrals and resulting actions will be tracked and reported on a quarterly basis to the VISN Director.

4. FOLLOW-UP RESPONSIBILITY: The Chief Network Officer (10N) is responsible for the contents of this directive. Questions on Persian Gulf War Veterans Programs can be directed to the Office of Public Health and Environmental Hazards (13), VA Central Office, 810 Vermont Avenue, NW, Washington, DC, 20420.

5. RESCISSION: This VHA Directive will expire January 30, 1998.



Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 2/19/97
FLD: VISN, MA, DO, OC, OCRO and 200-FAX 2/19/97
EX: Boxes 104, 88, 63, 60, 54, 52, 47 and 44 - FAX 2/19/97

ATTACHMENT D
(THE HONORABLE LANE EVANS)

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

IL 10-97-014

In Reply Refer To: 131

March 18, 1997

UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER

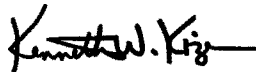
VHA's SERVICE EVALUATION AND ACTION TEAM (SEAT)

1. The Service Evaluation and Action Team (SEAT) Program was developed and approved on January 6, 1997. The final program plan including the purpose, policy, and required actions and responsibilities was presented by the Under Secretary for Health to the Directors of the 22 Veterans Integrated Service Networks (VISNs) on January 22, 1997.
2. Veterans Health Administration (VHA) Directive No. 97-008, February 19, 1997, establishes a SEAT within each VISN office to enhance VHA's responsiveness to patient needs and service satisfaction. The SEAT enables all medical center Directors, VISN Directors, and program staff at VHA Headquarters to track trends in customer concerns and complaints and to conduct an evaluation on a periodic basis. The SEAT provides a mechanism for each VISN office to continually assess opportunities to enhance the effectiveness of Department of Veterans Affairs (VA) clinical programs and to respond to veterans' concerns. The initial SEATs will be piloted with Persian Gulf Veterans Programs and, if successful, expanded to other program areas in the future.
3. The SEAT will receive input from national and local customer satisfaction surveys, the patient representative tracking program, veterans, veterans service organizations, helpline inquiries, and quality improvement programs. The Chairperson of the Network SEAT is responsible for collecting data obtained from these sources and maintaining this information at the VISN office. Each Network SEAT Chairperson is encouraged to process this aggregate information (by issue, by service, or by gender), and submit a consolidated quarterly report to their respective Network Director. A copy of this quarterly report needs to be submitted through the Chief Network Office (10NC), to Environmental Agents Service (131), VHA Headquarters, 810 Vermont Avenue N.W., Washington, DC 20420.
4. SEATs are being formed to:
 - a. Improve the responsiveness of VA health care delivery;
 - b. Improve communication with veterans, their families, and other stakeholders, where possible; and
 - c. Listen to and monitor trends in veterans' (individual or group) concerns about health care access, appropriateness, quality and fulfillment of VA program mandates within the VISN or at its medical facilities.

IL 10-97-014
March 18, 1997

5. The teams, are comprised of at least eight members, representing a variety of disciplines and interests, including veterans, quality improvement specialists, patient representatives and clinicians.

6. The information gathered on reported concerns, and recommendations for favorable resolution, will be referred to local medical facility staff for action. The SEAT monitoring of such action and results will allow VAH to continuously improve and enhance Persian Gulf Programs in the future.



Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

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ATTACHMENT E
(THE HONORABLE LANE EVANS)

**Department of
Veterans Affairs**

Memorandum

Date: October 30, 1996
From: Director, Environmental Agents Service (131)
Subj: Video Cassette, Satellite Video Teleconference: "Exposure of Persian Gulf Veterans to Chemical Warfare Agents at Khamisiyah: A Clinical Update"; October 21, 1996
To: All VA Medical Center Chiefs of Staff

1. On October 21, 1996, Environmental Agents Service, in conjunction with the St. Louis Education Center and the National Media Development Center, broadcast a satellite video teleconference describing events at the Khamisiyah Ammunition Storage Area in southern Iraq. This depot was detonated by U.S. troops in March 1991. The demolition work resulted in probable exposure of Persian Gulf veterans to chemical warfare nerve agents. Since last minute technical problems prevented some medical centers from receiving the satellite transmission, we are making the broadcast available to you on the enclosed video cassette.

2. The video teleconference featured VA and Department of Defense (DoD) health scientists and program officials, who described the known effects of acute exposure to various concentrations of chemical warfare nerve agents, and explained the symptoms that veterans could report as a result of such exposures. The panel also discussed the scientific basis for the development of chronic or delayed long-term health consequences experienced by exposed individuals, and described the health care programs available to Persian Gulf veterans concerned about exposures in the Gulf War.

3. The teleconference was designed for VA and DoD health care providers (physicians, nurses, physician assistants, social workers, registry coordinators, vet center staff), VBA regional office staff, and benefits counselors. We urge you to use the video for Continuing Medical Education (CME) conferences and have medical center staff view this video cassette.

4. If you have any questions or request additional information, please contact John E. Kraemer at (202) 273-8462.



Frances M. Murphy, M.D., M.P.H.
Director, Environmental Agents Service (131)

Enclosure

ATTACHMENT F
(REFER TO PAGE A-10)
(THE HONORABLE LANE EVANS)

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 96-051

August 14, 1996

VETERANS HEALTH ADMINISTRATION SPECIAL EMPHASIS PROGRAMS

1. **PURPOSE:** The purpose of this Directive is to establish Veterans Health Administration (VHA) policy and support for its Special Emphasis Programs (SEP) and to set forth national performance measures for the SEPs. One of the cornerstones of the Department of Veterans Affairs (VA) has been its SEPs which provide critical services for thousands of veterans who rely on VA for their care. In the "new VA," VHA will remain strongly committed to these programs.

2. BACKGROUND

a. The mission of VHA is to serve the needs of America's veterans. It does this by providing specialized care, primary care, and related medical and support services. The vision of the "new VA" is a healthcare system that supports innovation and accountability. It will provide a continuum of high quality healthcare in a convenient, responsive, caring manner – and at a reasonable cost.

b. One of the major challenges facing VHA is keeping the entire healthcare system, including the SEPs, viable and strong in light of unprecedented budget constraints. In order to achieve this, VA must adapt to the best practices of the private sector, and rigorously measure and monitor performance and outcomes to achieve greater cost effectiveness. This is especially important for the SEPs that are central to VA's mission.

3. **POLICY:** It is VHA's policy that the Special Emphasis Programs, as an essential and critical part of VHA, will be assessed utilizing the performance measures found in Attachment A to ensure the ongoing successful functioning of these programs. The designated SEPs are as follows:

- a. Blind Rehabilitation Service (BRS)
- b. Geriatrics and Long-Term Care Program
- c. Homeless Veterans Treatment and Assistance Programs
- d. Persian Gulf Veterans Program
- e. Post-Traumatic Stress Disorder (PTSD) Program
- f. Preservation Amputation Care and Treatment (PACT) Program
- g. Prosthetic and Sensory Aids Service
- h. Readjustment Counseling Service
- i. Seriously Mentally Ill Veterans Program
- j. Spinal Cord Injury/Dysfunction Program
- k. Substance Abuse Services Program
- l. Women's Veterans Health Program

4. **ACTION:** SEPs are a vital part of VHA's integrated healthcare system, and they will remain identifiable high priority programs as we move forward in creating the "new VA."

THIS VHA DIRECTIVE EXPIRES AUGUST 14, 2001

VHA DIRECTIVE 96-051**August 14, 1996**

Essential to the success of the SEPs is VHA's ability to support these programs by providing full-service healthcare.

a. The SEP Directors at VHA Headquarters, are responsible for:

- (1) Developing and updating, as necessary, the mission for the SEPs;
- (2) Developing policies and procedures for the SEPs;
- (3) Developing, in conjunction with the Office of Policy, Planning, and Performance, the performance measures for the SEPs;
- (4) Reviewing and analyzing the results of the performance measures;
- (5) Identifying systemwide SEP issues, and working with VHA Headquarters Patient Care Services; the Network Office; the Office of Policy, Planning, and Performance; the Veterans Integrated Service Networks (VISN); and others as needed, to determine the policy implications;
- (6) Developing and promoting strategies to effect systemwide changes;
- (7) Assessing the effectiveness of the SEPs from national, regional, and clinical perspectives, and altering the procedures, processes, and performance measures as necessary;
- (8) Identifying specific issues for integration into VHA's strategic planning and resource allocation systems; and
- (9) Assisting Network Directors and facility management to resolve issues regarding SEPs.

b. The Office of Policy, Planning, and Performance is responsible for:

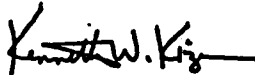
- (1) Assisting the SEPs develop program performance measures;
- (2) Assisting the SEPs identify systemwide issues;
- (3) Collecting the national performance (population) measures data for the SEPs; and
- (4) Providing the Networks and treatment facilities, VHA Headquarters, SEP Directors, and others as necessary, with nationally trended data that can be utilized by individual facilities to improve their services.

c. The Network Directors are responsible for:

- (1) Ensuring that the requirements of this VHA Directive are implemented within the Network, and that SEP activities are maintained, wherever feasible, within Network facilities;
- (2) Providing technical assistance, training, and consultation as needed; and

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August 14, 1996

- (3) Reviewing the SEP reports for Network trends.
- d. The Medical Center Director is responsible for:
- (1) Designating the appropriate professional(s) to be responsible for coordinating SEP activities;
- (2) Ensuring that the SEPs meet all the requirements delineated in VHA policies and procedures, as well as the requirements of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) and other relevant accrediting bodies;
- (3) Deciding the SEP activities conducted at the facility, including the integration of inpatient and outpatient activities;
- (4) Reviewing results of performance data from the SEPs, taking steps to improve performance as appropriate, and evaluating the effectiveness of the actions on an ongoing basis.
5. REFERENCE: Prescription for Change, Healthcare Value Begins with VA, 1996.
6. FOLLOW-UP RESPONSIBILITY: Performance Management Office (105A), Office of Policy, Planning, and Performance (105), and Directors, Special Emphasis Programs, Patient Care Services (11), are responsible for the contents of this Directive. Questions regarding this Directive may be directed to the Director, Performance Management Office, at 202-273-8936.
7. RESCISSION: This VHA Directive expires August 14, 2001.



Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

Attachment

DISTRIBUTION: CO: E-mailed 8/20/96.
FLD: VISN, MA, DO, OC, OCRO, and 200 - FAX 8/20/96
EX: Boxes 104, 88, 63, 60, 54, 52, 47, and 44 - FAX 8/20/96

ATTACHMENT A

BLIND REHABILITATION SERVICE

The mission of the Blind Rehabilitation Service is to improve the quality of life for blinded veterans by assisting them to develop the skills and capabilities needed for the attainment of personal independence and emotional stability. This is accomplished through identification of visually impaired veterans, provision of comprehensive inpatient and outpatient rehabilitation services, education of blinded veterans and their families, and research.

Population Measures

1. Blinded veterans demonstrate post rehabilitation improvement in functional status 6 months after discharge from a comprehensive VA blind rehabilitation program.
GOAL: 80%
2. Percentage of blinded veterans who receive VA blind rehabilitation outpatient services pre- and-post inpatient rehabilitation will realize shortened length of stay in the VA inpatient Blind Rehabilitation Program.
GOAL: 100%
3. Blinded veterans identified by a Visual Impairment Services Team (VIST) coordinator as needing blind rehabilitation will have access to a comprehensive inpatient blind rehabilitation program within 6 months.
GOAL: 100%
4. Percentage of fully or highly satisfied patients on National Blind Rehabilitation Service Customer Satisfaction Questionnaire.
GOAL: 85%

Program Measures

1. The number of blinded veterans on VIST rolls reflects the incidence of blindness of eligible blinded veterans in the VISN veteran population.
2. Percentage of eligible blinded veterans scheduled for evaluation for inpatient blind rehabilitation treatment within 30 days of identification.
GOAL: 100%
3. Percentage of blinded veterans on VIST rolls offered an annual review, which includes a yearly physical and eye exam, benefits review and blind rehabilitation evaluation.
GOAL: 100%
4. Percentage of veterans on VIST rolls satisfied with VIST services.
GOAL: 95%

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5. Percentage of veterans on Blind Rehabilitation Outpatient Specialist (BROS) rolls satisfied with BROS services.
GOAL: 95%
6. Percentage of blinded veterans receiving recommended prosthetics equipment within 30 days of discharge from BRC Program.
GOAL: 95%

GERIATRICS AND LONG-TERM CARE PROGRAM**HOME-BASED PRIMARY CARE (HBPC)**

The mission of the Geriatrics and Long-Term Care program is to provide health care and related support services for aged and other veterans requiring long-term care. This is accomplished through identifying needs and determining the setting most conducive to meeting these needs, while maintaining functional independence. Services are offered through a number of programs including Home Based Primary Care (formerly known as Hospital-Based Home Care); VA, Community, and State Nursing Home Care; Community-Based Long-Term Care; Geriatric Research, Education and Clinical Centers (GRECC); Geriatric Evaluation and Management Programs (GEMs); and State Home Construction and Per Diem Grants.

The mission of the Home-Based Primary Care (HBPC) program is to provide primary care, delivered by an interdisciplinary team of VA staff to homebound (often bedbound) patients for whom return to an outpatient clinic is not practical.

Population Measures

1. Patient satisfaction with HBPC.
GOAL: 95%
2. Initial contacts with the HBPC patient are made within 2 working days from the time of hospital discharge.
GOAL: 100%

Program Measures

1. HBPC programs are coordinated with the fee-basis or Medicare referral and/or home health aide services.
GOAL: 50%
2. Establish methodology for unit cost comparison of HBPC primary care versus alternative methods of such care.
GOAL: Establish baseline

VHA DIRECTIVE 96-051**August 14, 1996****GERIATRICS AND LONG-TERM CARE PROGRAM****VA, COMMUNITY, AND STATE NURSING HOME CARE**

The mission of the Geriatrics and Long-Term Care program is to provide health care and related support services for aged and other veterans requiring long-term care. This is accomplished through identifying needs and determining the setting most conducive to meeting these needs, while maintaining functional independence. Services are offered through a number of programs including Home Based Primary Care (formerly known as Hospital-Based Home Care); VA, Community, and State Nursing Home Care; Community-Based Long-Term Care; Geriatric Research, Education and Clinical Centers (GRECC); Geriatric Evaluation and Management Programs (GEMs); and State Home Construction and Per Diem Grants.

VA's nursing home care mission is to meet a portion of veteran demand for nursing home care through the VA operated Nursing Home Care Units, Community (Contract) Nursing Homes, and State Home Nursing Homes.

Population Measures

1. Patient and family satisfaction with nursing home care.
GOAL: 95%
2. Percentage of older (65+) veterans who use VA health care and receive nursing home care through VA-sponsored program (VA-operated, community, state home).
GOAL: 8%
3. Percentage of Nursing Home patients returned to hospital (Absent-Sick-In-Hospital).
GOAL: 15%
4. In VA Nursing Home Care Units, the percent increase in number of patients with high complexity Resource Utilization Group scores.
GOAL: 5%

Program Measures

1. The number of Multi-State Contract initiatives executed.
GOAL: 6
2. Percent of the CNH budget expended through Multi-State Initiated (M-SCI) contracting.
GOAL: 10%
3. Percent of patients with a Patient Assessment Instrument (PAI) completed for CNH placements.
GOAL: 50%

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GERIATRICS AND LONG-TERM CARE PROGRAM**COMMUNITY BASED LONG-TERM CARE**

The mission of the Geriatrics and Long-Term Care program is to provide health care and related support services for aged and other veterans requiring long-term care. This is accomplished through identifying needs and determining the setting most conducive to meeting these needs, while maintaining functional independence. Services are offered through a number of programs including Home Based Primary Care (formerly known as Hospital-Based Home Care); VA, Community, and State Nursing Home Care; Community-Based Long-Term Care (CBLTC); Geriatric Research, Education and Clinical Centers (GRECC); Geriatric Evaluation and Management Programs (GEMs); and State Home Construction and Per Diem Grants.

The mission of Community-Based Long-Term Care Programs is to provide contract adult-day health care and homemaker/home health aid services to veterans who are at a nursing home level of need.

Population Measures

The amount of funds expended for CBLTC expressed as percentage of the community nursing home budget.

GOAL: 5%

Program Measures

1. CNH funds are expended on the CNH Program or alternative community-based long-term care services (CBLTC).
GOAL: 100%
2. Percent increase in VA facilities participating in CBLTC (The baseline is 110 facilities).
GOAL: 20%

August 14, 1996

GERIATRICS AND LONG-TERM CARE PROGRAM

GERIATRIC RESEARCH, EDUCATION AND CLINICAL CENTERS (GRECCs)

The mission of the Geriatrics and Long-Term Care program is to provide health care and related support services for aged and other veterans requiring long-term care. This is accomplished through identifying needs and determining the setting most conducive to meeting these needs, while maintaining functional independence. Services are offered through a number of programs including Home Based Primary Care (formerly known as Hospital-Based Home Care); VA, Community, and State Nursing Home Care; Community-Based Long-Term Care; Geriatric Research, Education and Clinical Centers (GRECC); Geriatric Evaluation and Management Programs (GEMs); and State Home Construction and Per Diem Grants.

The mission of the GRECC Program is to improve services that are maximally effective and appropriate in meeting the medical, psychological and social needs of older veterans, through:

1. Geriatric and gerontological research;
2. Training of health personnel and trainees in the provision of health care to older individuals; and
3. Development and evaluation of improved models of clinical services.

Population Measures

Data on effectiveness of GRECC clinical demonstration projects in improving patient outcomes is reported annually with recommendations for replication at other VA sites, as indicated by the data.

GOAL: 100%

Program Measures

Research:

1. The number of scientific papers authored/ co-authored each year by each GRECC research investigator (primary investigator or co-investigator on an active research project) in peer-reviewed journals (List Journals).
GOAL: ≥ 1
2. Percent of publications in peer reviewed-journals by GRECC core staff listing their VA affiliation.
GOAL: 100%

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Education and Training:

3. Number and percent of GRECC host facility clinical staff (includes physicians and all associated health staff) who are offered education/training in caring for elderly veterans by the GRECC.
GOAL: -->95%
4. Number of clinical staff at other VA facilities who receive education/training in caring for elderly veterans in the GRECC.
GOAL: Establish baseline in 1st year
5. Percent of geriatric fellows (PGY 4 and 5 residents) and VA funded associated health trainees in geriatrics (e.g. advanced geriatric nurse practitioners, geriatric pharmacy residents, geropsychology postdoctoral fellows) who received a substantial portion of their specialized geriatric training from the GRECC and are practicing geriatrics/gerontology or have academic appointments involving geriatrics/gerontology 2 years after completion of training.
GOAL: Establish baseline
6. Number of ongoing clinical demonstration projects at each GRECC which annually evaluate and report on the project's effectiveness in delivering improved clinical services to the elderly.
GOAL: >=1

Consultation and Outreach

7. Number of improvements each year in geriatric research, education or clinical activity at each GRECC host facility as a result of GRECC consultation.
GOAL: >=1
8. Number of improvements each year in geriatric research, education or clinical activity at other VAMCs as a result of consultation/outreach from the GRECC.
GOAL: >=1

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August 14, 1996

GERIATRICS AND LONG-TERM CARE PROGRAM

GERIATRICS EVALUATION AND MANAGEMENT (GEM)

The mission of the Geriatrics and Long-Term Care program is to provide health care and related support services for aged and other veterans requiring long-term care. This is accomplished through identifying needs and determining the setting most conducive to meeting these needs, while maintaining functional independence. Services are offered through a number of programs including Home Based Primary Care (formerly known as Hospital-Based Home Care); VA, Community, and State Nursing Home Care; Community-Based Long-Term Care; Geriatric Research, Education and Clinical Centers (GRECC); Geriatric Evaluation and Management Programs (GEMs); and State Home Construction and Per Diem Grants.

The mission of the GEM Program is to enhance the quality of life for selected elderly veterans, by improving clinical care, diagnosis, polypharmacy, discharge planning, functional status, and utilization. The GEM Program also provides a site for geriatric education and clinical research.

Population Measures

Percentage of frail elderly veterans who received VA GEM services and were discharged to home or community residential setting.

GOAL: 65%

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GERIATRICS AND LONG-TERM CARE PROGRAM**STATE HOME PER DIEM GRANTS**

The mission of the Geriatrics and Long-Term Care program is to provide health care and related support services for aged and other veterans requiring long-term care. This is accomplished through identifying needs and determining the setting most conducive to meeting these needs, while maintaining functional independence. Services are offered through a number of programs including Home Based Primary Care (formerly known as Hospital-Based Home Care); VA, Community, and State Nursing Home Care; Community-Based Long-Term Care; Geriatric Research, Education and Clinical Centers (GRECC); Geriatric Evaluation and Management Programs (GEMs); and State Home Construction and Per Diem Grants.

The State Home Per Diem Grant Program assists States in the cost of care provided veterans in State homes recognized by VA. The assistance to States through this grant program promotes Federal-State sharing in meeting part of the veteran demand for institutional long-term care.

Population Measures

1. Compliance with the quality of care standards for the level(s) of care provided by the state home (domiciliary, nursing home, hospital) is documented and reported by the VA facility of jurisdiction annually and as indicated.
GOAL: 100%
2. Correction of quality of care and/or life safety deficiencies by the state home according to specified timeframe is documented and reported by the VA facility of jurisdiction.
GOAL: 100%

Program Measures

1. Analysis of current per diem rates and recommendations for increases in rates are completed.
GOAL: Annually
2. Budget plan for existing and planned census in State Home domiciliary, nursing home and hospital levels of care are developed following submissions by the VA facility of jurisdiction.
GOAL: Annually
3. Analysis of budget plan and adjustments based on actual census data is completed.
GOAL: Quarterly
4. Inspection reports indicating level of compliance with established standards of care are provided to the State Home within 15 workdays of the VA inspection by the facility having jurisdiction over the Home.
GOAL: 90% (after establishing baseline)

August 14, 1996

PERSIAN GULF VETERANS

The mission of the Persian Gulf (PG) Veterans Program is to provide strategic direction for the clinical, research, education and outreach programs for PG veterans. This is accomplished by working in collaboration with other VA offices; Federal, state, and local government agencies; and nonprofit community and private providers. The Persian Gulf Veterans Program also serves as VHA's liaison to the Persian Gulf Veterans Interagency Coordinating Board.

Population Measures

1. Waiting time for appointment for Registry examination and referral center admission.
GOAL: ≤ 30 days in 95% of VAMCs
2. Education
 - a. Provide opportunities for continuing medical education of Persian Gulf War (PGW) health issues.
GOAL: National Training Program
 - (1) Onsite conference (8/27-8)
 - (2) Teleconferences (satellite video broadcasts) Two in 1996
 - b. Provide current information on PGW programs, legislation, reports and publications.
GOAL: Quarterly mailouts and newsletter, periodic Environmental Agents Service (EAS) conference calls
3. Future - PGW veteran satisfaction with VA healthcare.
GOAL: Satisfaction $\geq$ other veteran groups

Program Measures

1. Waiting times for appointments for consultations, e.g., neurology, rheumatology, gastroenterology, psychiatry, psychology, etc.
GOAL: ≤ 45 days
2. Persian Gulf Registry: Phase I and Phase II code sheet rejection rates.
GOAL: rate $\leq 5\%$
3. Time to correct rejected code sheets.
GOAL: ≤ 30 days
4. Compliance threshold on the annual Quality Management monitor for Persian Gulf Registry Examinations as measured against selected clinical indicators.
GOAL: 90%

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5. Participation rates of Persian Gulf Coordinators and Registry Physicians in information and educational activities, i.e., quarterly Environmental Agents Service conference calls, satellite video-television broadcasts, and continuing medical education conference.

GOAL: 75%

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POST TRAUMATIC STRESS DISORDER (PTSD)

The mission of the Post Traumatic Stress Disorder Program is to provide treatment for veterans suffering from PTSD and to prevent relapse. This is accomplished by providing supportive mental health services and coordinating PTSD research and education.

Population Measures

1. Percentage of veterans scoring equal or better in PTSD symptoms on the short form of the Mississippi Scale 4 months after discharge.
 GOAL: 85%
2. Percentage of veterans scoring equal or better in substance abuse symptoms as measured by the Alcohol and Drug Subscales of the Addiction Severity Index (ASI) 4 months after discharge.
 GOAL: 69%
3. Percentage of veterans equal or improved in occupational functioning as measured by the number of days employed during the past 30 days at 4 months after program discharge.
 GOAL: 86%
4. Proportion of veterans in need of PTSD care treated for PTSD in VA outpatient mental health clinics in each year.
 GOAL: 55%
5. Proportion of veterans who receive a psychiatric outpatient visit within 30 days of discharge from an inpatient program (from HEDIS 2.5).
 GOAL: >51%

Program Measures

1. Proportion of veterans successfully contacted for outcome assessment after discharge from an inpatient PTSD program.
 GOAL: 50%
2. Number of patients seen per FTEE allocated to the outpatient PTSD program (including facility contributed FTEE).
 GOAL: 75 Patients/FTEE
3. Number of hospital days for patients in the 6 months after discharge from an inpatient PTSD program.
 GOAL: <13.5 days

August 14, 1996

PRESERVATION-AMPUTATION CARE AND TREATMENT (PACT) PROGRAM

The mission of the Preservation Amputation Care and Treatment Program is to reduce the incidence of amputations and other complications due to diabetic foot ulcers and peripheral vascular disease. This is accomplished by an interdisciplinary program of care and treatment and by tracking of patients with amputations and those persons identified as "at risk" for limb loss.

Population Measures

1. The incidence of lower extremity amputations among veterans with diabetes.
GOAL: Reduce by 5% from prior year
2. Percentage of diabetics with chart documented annual lower extremity ulcer risk examination.
GOAL: Increase by 5% from prior year
3. Percentage of new lower extremity amputees who achieve functional status adequate to return to pre-hospital living setting.
GOAL: 85%
4. Percentage of new lower extremity amputees who are ambulatory six months after provision of artificial limb.
GOAL: Increase by 3% from prior year

Program Measures

1. Percentage of new amputees, i.e., toe, transmetatarsal, below knee, above knee, and hip disarticulation referred by the PACT Coordinator for evaluation.
GOAL: 100%
2. Percentage increase in the number of new outpatients identified as being at-risk of limb loss who are referred to the PACT Program.
GOAL: >Prior Year

VHA DIRECTIVE 96-051**August 14, 1996****PROSTHETIC AND SENSORY AIDS SERVICE**

The mission of the Prosthetic and Sensory Aids Service is to serve as case manager for the physically disabled veteran and to provide quality prosthetic and sensory aid services to these patients. This is accomplished by furnishing properly prescribed prosthetic equipment, sensory aids and assistive devices.

Population Measures

1. Percentage of veterans fitted for a limb within 30 days of amputation.
GOAL: Establish baseline
2. Percentage of prosthetic patients who respond favorably on the Prosthetic Patient Satisfaction survey.
GOAL: >97%
3. Percentage of prosthetic patients with improved functional status 6 months post fitting.
GOAL: Establish baseline

Program Measures

1. Average VA waiting time for an appointment for examination and prescription of a prosthetic appliance will be equal to or less than local community standards, e.g., Optometry, Audiology, Orthopedics, Spinal Cord Injury, Physical Medicine and Rehabilitation, etc.
GOAL: Establish baseline
2. Number of delays in prosthetic orders, per month per total number of orders, i.e., orders not placed within 5 days.
GOAL: <2% of workload
3. Number of Type I recommendations from JCAHO/CARF surveys concerning the management of Durable Medical Equipment and the Home Oxygen Program in accordance with JCAHO Home Care standards.
GOAL: 0
4. Quarterly Prosthetic Needs/Excess Reports will accurately report on PSAS cost accounts. Funding will be based upon a strong correlation between obligations and workload.

(Centralized Prosthetic Fund Annual Facility Budget)

\$5 million and up	(+/-) <2%
\$4 million to <\$5 million	(+/-) 2%
\$3 million to <\$4 million	(+/-) 3%
\$2 million to <\$3 million	(+/-) 4%
\$1 million to <\$2 million	(+/-) 5%
\$500,000 to <\$1 million	(+/-) 6%
\$500,000	(+/-) 10%

5. Number of PSAS Headquarters-initiated program site visits to ensure compliance with national fiscal policy (continuation of PIIP objective).
GOAL: 24/FY

VHA DIRECTIVE 96-051**August 14, 1996****READJUSTMENT COUNSELING SERVICE VETERAN CENTERS**

The mission of the Readjustment Counseling Service is to restore normal emotional functioning to persons psychologically injured during military service. This is accomplished by providing outreach, crisis intervention, and "holistic" counseling services to eligible veterans and their families. These services are provided through a network of readjustment counseling centers commonly known as "vet centers."

Population Measures

1. The rate of special population veterans at risk for PTSD and other readjustment problems accessing RCS care. Special populations include veterans with high combat exposure, sexual trauma, physical disability, or ethnic diversity.

GOAL: Contact with the percentage of veterans predicted to be at risk in the Vet Center's catchment area

2. Percent of clients satisfied with services.

GOAL: Obtain baseline information

3. Post-treatment problem severity.

GOAL: Improvement in problem severity ratings post-treatment

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August 14, 1996

SERIOUSLY MENTALLY ILL VETERANS

The mission of the Seriously Mentally Ill Veterans Program is to optimize the functioning of seriously mentally ill veterans. This is accomplished by providing state-of-the-art treatment across a continuum of inpatient and outpatient settings.

Population Measures

1. Percentage of SC veterans with a diagnosis of psychosis who use VISN mental health services.

GOAL: $\geq 39\%$

Note: Adjusted for sociodemographic factors and availability of non-VA services. From Table 2-4, National Mental Health Program Performance Monitoring System (NMHPPMS), June 14, 1996, Northeast Program Evaluation Center (NEPEC)(182), VA Medical Center, 950 Campbell Ave., West Haven, CN 06516, (203) 937-3850; FTS (700) 428-3717.

2. 30 day psychiatric re-admission rates (excluding substance abuse), within the VISN.

GOAL: $< 15\%$

Note: See table 3-1, (NMHPPMS)

3. Functional performance 6 months and 1 year after initiating treatment in Intensive Psychiatric Community Care (IPCC) as measured by a standard Instrumental Activities of Daily Living (IADL) instrument.

GOAL: 20% improvement over previous year

4. Overall score on the outpatient domain of the mental health performance index which includes measures of access, utilization of services, and continuity of care.

GOAL: 20% improvement over previous year

5. Percentage of veterans who receive an outpatient appointment within 30 days of discharge from an inpatient program.

GOAL: $\geq 45\%$

Note: See table 4-1, (NMHPPMS)

Program Measures

1. Average VISN general psychiatric bed days of care during the 6 months after discharge.

GOAL: < 14 days

Note: See table 3-1, (NMHPPMS)

2. The number of 2 month periods (by VAMC) in which general psychiatric outpatients have two or more VA outpatient mental health visits (continuity of care) within the first 6 months following discharge.

GOAL: ≥ 1.13

Note: See table 4-7, (NMHPPMS, adjusted for patient characteristics, resident distance from VA, etc.)

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3. The percentage decrease in the number of SMI veterans per VISN with a diagnosis of psychosis with lengths of stay of 100 days or longer.
GOAL: $\geq 10\%$
4. The percentage decrease in average length of stay of psychiatric inpatients within 28 VAMCs identified as significant outliers.
GOAL: $\geq 10\%$

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August 14, 1996

SPINAL CORD INJURY/DYSFUNCTION

The mission of Spinal Cord Injury/Dysfunction Program (SCI/D) is to assist veterans with SCI/D to develop the capacities needed to attain personal independence and lifelong health and well being. This is accomplished by providing initial functional rehabilitation, preventive care, sustaining care, and long-term care across a continuum of inpatient and outpatient settings.

Population Measures

1. Percentage of SCI/D patients responding favorably on satisfaction surveys concerning communication, courtesy, quality of care, timeliness, and clinical environment.
 GOAL: 90%
2. Overall score on the SCI/D evaluation index (characteristics include measures of effectiveness - outcomes achieved by persons served; efficiency; and other elements to be defined). A baseline report is expected in January.
 GOAL: Improvement
3. Percentage of eligible SCI/D veterans receiving annual evaluation as required by M-2, part XXIV.
 GOAL: >80%

Program Measures

1. Percent of SCI/D patients who are assigned to a primary care provider.
 GOAL: 90%
2. Established use of an appropriate functional outcome measure (such as FIM) for SCI/D patients.
 GOAL: 100%
3. Percentage of eligible veterans with a diagnosis of SCI/D who used a VISN SCI support clinic or center in 1996.
 GOAL: Exceed FY 95 Baseline
4. Percentage of SCI/D patients with semi-emergent conditions admitted to an SCI Center within 2 weeks of acceptance. Semi-emergent conditions and triage criteria will be defined.
 GOAL: >95%

SUBSTANCE ABUSE SERVICES

The mission of the Substance Abuse Services Program is to provide programs that identify, manage and treat substance use disorders. This is accomplished by providing early intervention, stabilization (including detoxification) and rehabilitation services, continuing care and monitoring services, staff education, and research.

Population Measures

1. The percentage of patients with active substance abuse who enter substance abuse treatment within 3 days of discharge from a hospitalization (including detoxification).
GOAL: 70%
2. The total number of patients in specialized acute, residential, domiciliary or ambulatory substance abuse care as a percentage of the total number of patients in care at the medical center.
GOAL: No decrease from prior fiscal year
3. The percentage of patients with a positive alcohol abuse screen in primary care settings who are abstinent at 6-month follow-up.
GOAL: 60%

Program Measures

1. For patients discharged from specialized acute care, residential and domiciliary substance abuse bed sections (whose entire index episode of inpatient care is in a substance abuse bed section):
 - a. percentage of patients who obtain two or more substance abuse or mental health outpatient visits in the 30 days after discharge.
GOAL: 70%
 - b. Number of days between discharge from inpatient care and the first visit.
GOAL: 7 days or less
2. Percentage of patients admitted directly to specialized substance abuse outpatient care who have two or more additional specialized outpatient substance abuse clinic contacts in the subsequent 30 days.
GOAL: 70%
3. The number of patients in specialized outpatient substance abuse as a percentage of the number of outpatients.
GOAL: No decrease in % from previous fiscal year.
4. The number of specialized outpatient substance abuse visits as a percentage of total outpatient visits.
GOAL: No decrease in % from previous fiscal year.

local agencies, as well as community non profit organizations and private entities.

Population Measures

1. Percentage of veterans who acquired secure living arrangements at discharge from a domiciliary or a residential treatment program.
GOAL: 40%
2. Percentage of veterans who obtained employment at discharge from a domiciliary or residential treatment facility.
GOAL: 18%
3. Percentage of veterans who acquired secure living arrangements at 6 months and 1 year after entry into the VA Supported Housing (VASH) Program.
GOAL: 80%
4. Percentage of veterans identified on the annual homeless census who receive a psychiatric outpatient visit within 30 days of discharge from an inpatient setting (from Health Plan Employer Data and Information Set (HEDIS) 2.5).
GOAL: >45%

Program Measures for Domiciliary Care for Homeless Veterans Program (DCHV)

1. Annual Turnover Rate of homeless veterans per DCHV bed per year which is defined as the number of discharges (determined by the number of monitoring forms received at NEPEC for which the discharge data falls within a given fiscal year) divided by the number of operational beds (as determined by an annual survey conducted on September 1st of each year).
GOAL: >1.4
2. Percentage of homeless veterans successfully completing DCHV treatment.
GOAL: >38%
3. Improvement in alcohol problems of veterans from the time they entered DCHV treatment to the time of discharge.
GOAL: >57%
4. Improvement in drug problems of veterans from the time they entered treatment to the time of discharge.
GOAL: >55%

VHA DIRECTIVE 96-051
August 14, 1996

Program Measures for Health Care for Homeless Veterans (HCHV)

1. Number of literally homeless veterans receiving intake assessments per clinical FTEE.
GOAL: >52 per year
2. Number of unique homeless veterans treated in an HCHV Program per clinical FTEE per year.
GOAL: >100
3. Percentage of homeless veterans successfully completing residential treatment programs.
GOAL: >30.4%
4. Percentage of veterans referred for follow-up treatment at the time of discharge from residential treatment.
GOAL: >60.8%
5. Improvement in alcohol problems of veterans treated from the time they entered residential treatment to the time of discharge.
GOAL: >52.5%
6. Percentage of veterans scoring equal or better in substance abuse symptoms as measured by the Alcohol and Drug Subscales of the Addiction Severity Index (ASI) 6 months and 1 year after entering the VASH program.
GOAL: 69%
7. Number of days hospitalized in the 6 months after discharge of veterans identified on the annual homeless census.
GOAL: <14 days

VHA DIRECTIVE 96-051
August 14, 1996

WOMEN VETERANS HEALTH PROGRAM

The mission of the Women's Veterans Health Program is to ensure equity of access to VA services and care for women veterans. This is accomplished through integration of clinical care, education, and research on women veterans-related issues.

Population Measures

1. Satisfaction with VA services.
 GOAL: Ratings comparable to men
2. Percentage of appropriate women 50-69 years of age receiving mammography within the last 2 years.
 GOAL: 100%
3. Percentage of appropriate women <65 years of age receiving cervical cancer screening within the last 36 months.
 GOAL: 100%

Program Measures

1. Number of focus groups conducted in each VISN to explore any gender specific differences in customer satisfaction measures.
 GOAL: ->1/year
2. Percentage of contracting pathology laboratories reviewing Pap smears that are accredited by CAP and hold a CLIA certificate.
 GOAL: 100%
3. Percentage of on-site pathology laboratories reviewing Pap smears that are accredited by CAP and percent of pathologists enrolled in the National Cytopathology Proficiency Program.
 GOAL: 100%
4. Percentage of women veterans receiving notification of Pap smear findings within one month of performance of the test.
 GOAL: 100%
5. Percentage of on-site mammography units accredited.
 GOAL: 100%
6. Percentage of women receiving mammograms notified of results within 1 month.
 GOAL: 100%



HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

APR 15 1997

Honorable Lane Evans
Ranking Democrat
Committee on Veterans Affairs
House of Representatives
Washington, DC 20515

Dear Representative Evans:

This letter is in response to your request of February 26, 1997, regarding the Full Committee on Veterans' Affairs hearing of February 11, 1997. The attachment includes *A Working Plan for Research on Persian Gulf Veterans' Illnesses* in response to the first question. (For enclosure, see page 47.)

I trust this information will be useful to you.

Sincerely,

Edward D. Martin

Edward D. Martin, M.D.

Acting Assistant Secretary of Defense

Attachment:
As stated

QFR from Honorable Lane Evers, Ranking Democratic Member,
House Committee on Veterans Affairs

Question: How could the DoD more effectively meet the needs of Gulf War veterans still on active duty and their family members?

Answer: Through the Office of the Special Assistant for Persian Gulf Illnesses, DoD has initiated a multifocal needs assessment of the Persian Gulf veteran active duty members and their family members to determine the full range of factors to consider in order to plan effective interventions. Among the strategies being employed are:

- deployment of a survey in January 1997, designed for a representative sample of the target population;
- assignment of a civilian physician familiar with expertise in risk communication who is the project manager to explore current approaches and shortfalls and design an effective risk communication program;
- revision of an interactive Internet web site, GulfLINK, which contains illustrative "case studies" which are educative in nature; and,
- initiation of active communication with the Military Alliance, organizations which interface regularly with the target population.

Question: How could DoD more effectively meet the needs of Guard and Reserve personnel who are Gulf War veterans and their family members?

Answer: The Department of Defense and the Department of Veterans Affairs have been collaborative members of the Persian Gulf Veterans Coordinating Board since January 1994. It is the consensus of both Departments that the most effective strategy for the DoD to more effectively meet the needs of Persian Gulf veteran Guard and Reserve personnel is to strengthen the referral process when a Persian Gulf veteran has completed the standardized DoD Comprehensive Clinical Evaluation Program. To this end, DoD informed all the physician CCEP points of contact at each MTF, to clearly guide the referral process for referrals made to a VA facility for Guard and Reserve Persian Gulf veterans seen in the CCEP.

Question: Describe the current health status of U.S. military personnel who served in the theater of operations during Desert Shield and/or Desert Storm.

Compare the health status of U.S. military personnel who served in the theater of operations during Desert Shield and/or Desert Storm with the status of U.S. military personnel on active duty during Desert Shield and/or Desert Storm who did not serve in the theater of operations.

Compare the current health status of U.S. military personnel who served in the theater of operations during Desert Shield and/or Desert storm with the status of non U.S. military personnel who also served in the theater of operations during Desert Shield and/or Desert Storm.

Answer: A variety of epidemiologic studies that can provide the answers to these questions is in progress or being planned. To date, epidemiologic studies that have looked at deaths and hospitalizations of Persian Gulf war veterans compared to non Persian Gulf war veterans have found no major differences between the two groups. To respond to these questions definitively, however, is premature.

Question: The Institute of Medicine's report indicated that Troop Exposure and Assessment Model (TEAM) and Registry of Unit Locations (RUL) will have limited utility for epidemiological studies since they provide information at the unit level rather than at the individual level. Is there any obstacle in ensuring that this type of information is gathered and maintained at the individual level in future conflicts?

Answer: Tracking troops at the individual level rather than the unit level presents a number of unique and highly complex problems from a technical, security, and financial standpoint. A number of security issues and concerns exist with an automated or electronic tracking system intended for individual troops, since individual troop location information, as well as total numbers, could also be tracked by a potential enemy. In addition, a system capable of tracking thousands of individuals would require substantial technical advancements from data transmission to data storage and interpretation perspectives. Questions arise as to how often individual location data would be required during a 24-hour period. Also, troop location data are of little value, without high quality environmental exposure data and acute health outcome information. In addition to the technical hurdles, security and safety issues, the financial obligation would be enormous for a system that could effectively track at the individual-person level.

One solution to the troop tracking problem would be to enhance the current system of unit tracking. This would require following smaller units in a more

thorough manner and ensuring we knew the individuals assigned to the unit at all times. This system combined with the improved environmental and medical data being gathered by DoD in current operations offers the most efficient solution to tracking troops during a deployment.

Question: In its report, the Institute of Medicine concluded that a number of elements should be developed to form a "Military Health Surveillance System that would increase the nation's capacity to address questions about acute and chronic health consequences of deployments of U.S. military service personnel". What is the status of DoD's implementation of IOM's recommendations on this subject?

Answer: The Charter for the Joint Medical Surveillance Policy Group has been established. The purpose of the JPMPG is to improve preventive medicine support for Joint military operations, advise the TRICARE Readiness Executive Committee, and act as preventive medicine information and coordination exchange among the Military Services. At the time of this response, a DoD Directive and DoD Instruction regarding the policy and implementation of joint medical surveillance is under formal coordination. These documents structure the approach the Department shall use to enable assessment of acute and chronic consequences of deployment. The program emphasizes the systematic collection of information for the identification of members of deployed units, assessment of health risk, accomplishment of standardized health screening assessments, and analysis of health outcomes possibly related to deployments. Elements of the surveillance policy are currently in place in Bosnia. The program will be disseminated throughout DoD by the end of FY 1997.

Question: The Presidential Advisory Committee's report mentioned DoD has been unresponsive to the recommendation that prior to any large deployment, DoD should undertake a through health evaluation of a large sample of troops to enable better post-deployment medical epidemiology. Why is DoD not responding to this recommendation?

Answer: Rather than targeting sample populations for assessment, the Department's position is that all deploying Service members of specified deployments receive pre- and post- deployment screening to include standardized health screening questionnaires with medical follow-up as clinically indicated. This policy was partially implemented in Bosnia and is being fully implemented for Southwest Asia. We expect the new medical surveillance policy to be formally adopted during 1997.

Question: Considering the concerns over the side effects of Pyridostigmine Bromide (PB) use when combined with exposures to other compounds, is DoD considering ending or temporarily prohibiting the use of PB? Does DoD see a need to keep records of individual PB use during wartime?

Answer: DoD will follow FDA requirements. If there is a significant risk that chemical warfare agents may be used against U.S. forces, the best available personal protective measures, including pre-treatment with pyridostigmine bromide, in conjunction with atropine and 2-PAM, remain our best tools to ensure that our troops are given the best chance for surviving a nerve gas attack. Doing everything possible to give our troops the best chance for survival is our bottom line. Concerning record keeping, the Department is exploring ways to appropriately document health related information for Service members within Theaters of Operation.

Question: In reviewing the Persian Gulf Registry records for veterans who were possibly within 50 km of the Khamisiyah Ammunition Storage Area during the demolition in March 1991, you testified 81 registry participants were diagnosed with musculoskeletal conditions at a higher rate than the 50 km or general registry group. Dr. Joseph, you testified a review of the CCEP participants which were within 50 km of Khamisiyah reported symptoms similar to Army CCEP participants. Please explain.

Answer: The Department has conducted preliminary descriptive analyses of the findings in the CCEP for the relatively small number of members of the units involved in the Khamisiyah demolitions and of the much larger group of individuals who were within the 50 km radius of Khamisiyah individuals in the CCEP. When compared to other groups of CCEP, participant members of those units which were involved in the demolition activities do appear to have a higher proportion of musculoskeletal diagnoses. The preliminary analysis of the self-reported symptoms of all CCEP participants within 50 km of Khamisiyah indicated that they were similar to other Army CCEP participants who were in the Khamisiyah area. Army CCEP participants were considered for comparative purposes rather than a heterogeneous mix of Army, Navy, or Air Force CCEP participants to represent an appropriate comparison group of which the majority of personnel operating near Khamisiyah were Army.

QFR from Honorable Luis Gutierrez,
Ranking Democrat Member, House Subcommittee on Health,
House Committee on Veterans Affairs

Question: Dr. Joseph, you state that an unknown illness or a syndrome that was mild or affected only very small proportion of veterans at risk might not have been detectable by the DoD Persian Gulf Registry.

Answer: The Department's Comprehensive Clinical Evaluation Program (CCEP) was designed as a clinical program to provide health care to veterans; it was not a formal epidemiologic study. The CCEP has provided important clinical information regarding the types of illnesses observed in CCEP participants as a group. These clinically apparent conditions are similar to those seen in primary practice. However, it is possible that among the over 25,000 individuals evaluated through the CCEP, there could either be a small number of individuals with unique conditions or others with mild symptoms and clinically unrecognizable diseases.

Question: Has the DoD commenced smaller sample size investigations to examine analogous patterns of illness in Gulf war veterans? This may allow the DoD to examine the possibility that hidden syndromes may effect certain groups of veterans.

Answer: DoD has initiated a comprehensive and integrated research program aimed at better understanding Gulf war veterans' illnesses. The research program includes projects within DoD, VA, HHS, U.S. and international universities, and other independent research organizations. Attached is A Working Plan for Research on Persian Gulf Veterans' Illnesses. The Working Plan lists all the projects in the current research portfolio.



Special Assistant
for
Gulf War Illnesses

OFFICE OF THE SECRETARY OF DEFENSE

1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000



1 APR 1997

Honorable Lane Evans
House of Representatives
Washington, D.C. 20515

Dear Congressman Evans:

This is in response to your recent letter requesting the answer to a question from the Committee on Veterans' Affairs on the accounting of troops who may have been exposed to chemical weapons that were destroyed at Khamisiyah. The answer you requested is enclosed.

I hope this information is helpful to the committee.

Sincerely,

Bernard Rostker

Enclosure



1. What is the status of DoD's accounting of troops who may have been exposed to chemical weapons that were destroyed at Khamisiyah? It is my understanding that General McCaffrey believes that all of the 24,000 men and women of the 24th Mechanized division were within 32 miles of the facility. Yet, of the 20,000 soldiers it currently estimates were possibly exposed, it lists only roughly 6,000 from the 24th.

Response: The registry of Gulf War units and unit locations is one of our top priorities. Dr. Rostker, the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses, met with General McCaffrey regarding the location of the 24th Infantry Division during the Gulf War. During that conversation, General McCaffrey suggested that since many of the records for his unit were not available, the Department should pursue two other potential sources of information. The first source was the 24th Infantry Division War Journal on file in the Army library and the second was to consult the operations officers who did the detailed planning of division operations and movements. The material in the Army library was reviewed; unfortunately, no new information was revealed. The Army is now preparing to bring together the Gulf War operations officers from the entire XVIIIth Airborne Corps, including the 24th Infantry Division. The Gulf War brigade and division operations officers will be assembled with maps and materials so that they can reconstruct the location of their units. This effort will begin by mid-April and should provide us additional insight into troop locations near Khamisiyah.

Representative Herbert Bateman Questions for the Record
Persian Gulf War Illnesses Hearing
February 11, 1997

Question:

Could the Department describe any changes it is implementing with regard to pharmacy privileges for military retirees? Please explain the rationale for any such changes.

Answer:

The Department's policy for providing pharmacy privileges for military retirees continues to follow existing applicable statutes. There has been no Departmental policy change regarding access to Military Treatment Facility (MTF) pharmacies. Recently there has been confusion with respect to restrictions of pharmacy services based on beneficiary classes. On April 4, 1997, we issued a reclarification of the policy regarding restrictions and dispensing prescriptions in military pharmacies. The memo clearly outlines current policy, which states that MTF pharmacies will fill all prescriptions for medications included on their local MTF drug list (formulary), independent of beneficiary category. Restrictions are permitted only for valid clinical reasons, specialty care, or protocols published by the Pharmacoeconomic Center. In those cases when a nonformulary product(s) is needed for a specific patient or a special treatment protocol, prior approval by the MTF commander is required to validate special clinical circumstances. To assure appropriate management of the authority to obtain nonformulary drugs to non-active duty beneficiaries, this authority is limited to prescriptions written by MTF providers. Under certain circumstances, nonformulary drugs may be needed and, therefore, must be available to active duty members who are central to the operational mission.

In addition, under the TRICARE program the Department has augmented the MTF pharmacy benefit through a mail order and retail pharmacy service for CHAMPUS and BRAC Medicare-eligibles living in regions with a TRICARE Managed Care Support Contractor. The Department is also in the process of establishing a National Mail Order Pharmacy program that will provide services to Active Duty members, MTF Prime enrollees, overseas beneficiaries, and BRAC Medicare-eligibles in Regions 1, 2 and 5.

Representative Herbert Bateman Questions for the Record
Persian Gulf War Illnesses Hearing
February 11, 1997

Question:

To the extent that changes are being implemented that restrict the ability of the military retirees to attain certain prescribed medications, does the department view this as a deterioration in the quality of retirement benefits that should have been brought to Congress' attention during deliberations on the current year's defense budget?

Answer:

There has been no Departmental policy change with respect to restricting the ability of military retirees to attain certain prescribed medications. It is the policy of the Department that MTF pharmacies will fill all prescriptions for items that are listed in their formulary (drug list), independent of beneficiary category. Restrictions are permitted only for valid clinical reasons, specialty care, or protocols published by the Pharmacoeconomic Center.

Representative Herbert Bateman Questions for the Record
Persian Gulf War Illnesses Hearing
February 11, 1997

Question:

What would the Department recommend as a way to fix whatever problems have resulted in the sudden inability of retirees to attain prescribed medications?

Answer:

Recently there has been confusion with respect to restrictions of pharmacy services based on beneficiary classes. On April 4, 1997, we issued a reclarification of the policy regarding restrictions and dispensing prescriptions in military pharmacies. The memo clearly outlines current policy, which states that MTF pharmacies will fill all prescriptions for formulary drugs, independent of beneficiary category. Therefore, restrictions are permitted only for valid clinical reasons, specialty care, or protocols published by the Pharmacoeconomic Center. In those cases when a nonformulary product(s) is needed for a specific patient or a special treatment protocol, prior approval by the MTF commander is required to validate special clinical circumstances. To assure appropriate management of the authority to obtain nonformulary drugs to non-active duty beneficiaries, this authority is limited to prescriptions written by MTF providers. For active duty patients, the facility must obtain the medication. It has been emphasized to the Surgeons General that it is incumbent upon them and their commanders to enforce this policy. However, supporting the operational mission may require that a nonformulary drug, not generally available to other DoD beneficiaries, be made available to an active duty member.

House Veterans Affairs Committee
February 11, 1997
DoD Actions Pertaining to the Persian Gulf Illness
Representative Robert A. Underwood
Dr. Stephen C. Joseph, M.D., M.P.H.

Question: I would like your proposal to ensure the Department of defense takes actions to facilitate participation of veterans in Guam and American Samoa in reporting symptoms and participating in research studies at no cost. As you know, the telecommunications market in Guam is such that veterans would be charged for use of 1-800 numbers. I ask that your plan to ensure no cost access to all programs by DoD or the VA with regard to hotline access, other reporting programs and research programs.

Answer: In support of Persian Gulf Veterans from Guam and Samoa, I propose the following authorization due to their unique circumstances. All Guamanian and Samoan Persian Gulf Veterans shall be allowed to call either of the 1-800 numbers from a military medical treatment facility located in either Guam or Samoa. At the time the call is placed, a member of the staff shall dial the number, and then allow the veteran privacy for the duration of the phone call. This will facilitate a direct referral from an MTF to a designated CCEP physician point of contact stateside. This information should be disseminated among the veteran population across both locations.

Researchers shall be informed of the availability of potential candidates at both locations that may be considered to enter research opportunities.

Answers from Dr. Philip Russell , Member, Committee to Review the Health Consequences of the Persian Gulf War, Institute of Medicine

Questions from The Honorable Lane Evans

Question 1.

A single, uniform, computerized medical record form and system covering all military personnel including National Guard and reserve units which contains data on hospital admissions, clinic visits, and other medical encounters (such as immunizations), and includes the individual's Department of Veterans Affairs record has been recommended.

What are the technological obstacles to accomplishing this record ? How much would it cost to develop and how long would development take ?

Answer: There are no technological obstacles to developing a medical record-keeping system that would meet the needs of the Armed Forces and the Department of Veterans Affairs. Adaptation of existing computer technology and data-base management methods will meet the requirements envisioned by the Committee. A commitment to cooperation among the agencies and program funding is needed. Service representatives indicated that developing and fielding such a system would take several years. No cost estimates were made although the committee recognized that the cost will be substantial.

Question 2:

In the report , the Committee stated that it was "entirely convinced that there are large numbers of sick veterans, some of them seriously disabled by their symptoms, that they need appropriate care and that active investigation into their problems must be continued ." In itself this is a very strong statement. Please elaborate why the Committee came to this conclusion.

Answer: The statement is based on analysis of several epidemiological studies of illness in Gulf War Veterans as well as the clinical data from the Department of Defense and Department of Veterans Affairs Persian Gulf Health Registries. The Gulf War veterans have all the diseases and illnesses expected in a population of similar size and demographic composition, in addition, some have had injuries or diseases known to have occurred during deployment such as leishmaniasis, further, stress related illnesses directly attributable to service in the Gulf War have been well document, and, finally, undiagnosed illness are reported. Although mortality, except for accidental death, has not increased in the population the statement regarding illness and disability is well justified by the available information.

Answer from Dr. Philip K. Russell, Member, Committee to Review the Health Consequences of the Persian Gulf War.

Question from The Honorable Luis Gutierrez:

Question:

Dr. Russell, the Presidential Advisory Committee's report explains that the Department of Defense does not test the health of our soldiers prior to their deployment in a active field of operations.

I believe that in order for our government to prevent future post-Gulf War situations, we must think in the long term by rigorously testing and recording data on our soldiers prior to their service overseas. If Congress must act to ensure that this is accomplished, then we must do so immediately.

As the new ranking Democrat on the Subcommittee on Health, I feel strongly that Congress must work on legislative means to see that our soldiers never return from war with unexplainable illness again.

Dr. Russell or Major Knox, what do you believe Congress can do to prevent future Gulf War crises ?

Answer: In my opinion the crisis was not caused by the casualties or illnesses per se. The crisis was caused by refusing health care to veterans, by the inability and the unwillingness to rapidly conduct thorough and credible epidemiological studies of the deployed population, and by the failure to provide timely, accurate and credible information on environmental exposures of military personnel.

Two major changes in the health care system are essential to avoid similar problems in the future. First, we must greatly improve the capability to keep medical records and to rapidly conduct epidemiological studies. Second, we must keep faith with our service members and provide appropriate access to medical care.

A computerized medical record system standardized throughout all Armed Service, National Guard and Reserves and Veterans Administration is needed to adequately monitor and assess the health of deployed units and the impact of deployment. Improved medical records plus a strengthening of the military Preventive Medicine capability will be very important in avoiding future crises. The second and, equally important change, is to provide health care to all returning veterans, regardless of the nature of their illness, for some substantial period after a combat deployment. We must recognize that it is impossible in many cases to know or to make a credible determination on whether a post deployment illness is related to the deployment or not. Veterans deserve the best care the nation can provide irrespective of presumptions regarding cause. Access to competent and compassionate medical care and rapid, thorough epidemiological investigations of unusual medical events will prevent medical problems from becoming political crises in the future.

Congressman Gutierrez to Veterans of Foreign Wars

"Is there any pattern you or your colleagues have detected with regard to the VA's rationale for rejecting some claims and covering others? Or, have you found this process to be haphazard and without consistency?"

The VFW feels there is, indeed, a pattern to the rationale used by the VA in rejecting many of the "Undiagnosed Illness" claims of Gulf War veterans. Of the claims denied that fall in this category, most are denied because the illness was not reported within twenty-four months of having left the region.

As of January 1, 1997, the VA has denied 94 percent (9,688 claims) of claims officially classified as Persian Gulf War (PGW) undiagnosed illnesses. Of those, 55 percent (5,386 claims) were based on the disclosure of symptoms beyond the two-year presumptive period. That percentage is the core of the our concern. Any denial solely because of symptom disclosure outside a set period of time is arbitrary when there is so much medical uncertainty currently surrounding PGW undiagnosed illnesses.

This point illustrates the need to temporarily establish an open-ended presumptive period for the manifestation and identification of symptoms relating to PGW undiagnosed illnesses. My colleagues and I have worked aggressively to ensure that our Gulf War veterans are not limited by time in seeking health care and compensation for what remains an unknown illness. I feel the recently announced extension of this period to a total of ten years is an encouraging step towards addressing the needs of our Gulf War veterans. My concern remains, however, that even this may not be enough time.

Section 106 in Title I of Public Law 103-446, *Veterans' Benefits Improvements Act of 1994* (November 2, 1994), required the Secretary to determine an appropriate presumptive period for considering claims on service connection for Persian Gulf War undiagnosed illnesses.

The law directed the VA to take into account three factors: (1) the current credible scientific and medical evidence; (2) the historical treatment afforded other disabilities with presumptive periods; and, (3) other pertinent circumstances regarding the experiences of PGW veterans.

Secretary Brown initially decided on a two-year period with the reasoning that "would provide an adequate period of time in which all veterans ... would have become aware of the potential significance of their symptoms and have had an opportunity to present and document [such] health concerns ..." (Veterans Benefits Administration fact sheet). That reasoning, of course, assumes a definite latency period to PGW symptoms, which can now be debated just alone on the unknown consequences of possible low-level chemical weapons exposure.

Until such time that there is some credible medical and/or scientific evidence as to what may be causing the unknown illnesses of our veterans, the VFW's position is clear -- any presumptive period must be open-ended. That, of course, is interpreted to be temporary. Once some credible evidence is available, the VA can then make rational decisions on the length of the presumptive periods for specific disabilities resulting from duty in the Southwest Asia theater of operations during the Persian Gulf War.

I feel the ten year presumptive period is a positive step. However, if it becomes apparent that this time frame is not long enough the VFW will be there to continue this fight for our Gulf War veterans.



For God and Country

March 26, 1997

The Honorable Lane Evans
Ranking Democratic Member
Committee on Veterans' Affairs
335 Cannon House Office Building
Washington, DC 20515

Re: Question Related to Hearing on February 11, 1997

Dear Congressman Evans:

Thank you for inviting The American Legion to testify at last month's hearing concerning Gulf War Illnesses and the Presidential Advisory Committee on Gulf War Veterans' Illnesses. The hearing was the most productive and well thought out to date on this important and emotional topic, and the Legion looks forward to future Gulf War hearings.

You have asked me to answer the following question: *What is your assessment of VA's health care for veterans with "Gulf War Syndrome" or Gulf War Illnesses? What improvements are needed in VA health care for these veterans?*

The VA Persian Gulf Registry was created to diagnose diseases and illnesses in Gulf War veterans with health complaints, or with health concerns, due to their service in the Persian Gulf. When a veteran reports symptoms of illness during a Registry exam, and a VA medical doctor cannot diagnose the illness causing the symptoms, the doctor reports that the symptoms are undiagnosed.

The Institute of Medicine considers the VA Persian Gulf Registry excellent for the diagnosis of illnesses.¹ However, 19.9 % of Gulf War veterans who have health complaints, and have received a VA Persian Gulf Registry examination, do not receive a diagnosis for some of their symptoms.² Successfully treating undiagnosed symptoms is a challenge for the entire medical community, not just the VA medical system. Tens of thousands of Gulf War veterans who have undergone a Registry exam receive a diagnosis for their health complaints. Both groups of veterans are eligible to receive medical treatment from the Department of Veterans Affairs if their current health complaints are more likely than not associated with Persian Gulf service. This liberal rule, by giving the veteran the benefit of the doubt, enables VA to offer medical treatment to tens of thousands of Gulf War veterans.

VA has not offered veterans standard clinical testing under current diagnostic strategies in primary care for fatigue. Veterans are, therefore, not likely to be treated appropriately for fatigue. Fatigue is the most widely reported symptom among veterans on the VA Registry.³ It is therefore unlikely that VA is offering effective or quality medical treatment to Gulf War veterans who suffer

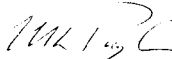
from fatigue. The quality of medical treatment offered to veterans who suffer from other symptoms has not been measured, and is unknown.

In the last fifteen years, outcomes research has examined the subjective experience of patients under real-world conditions. The goal has generally been not to test the efficacy of interventions ("can drug treatment for depression make patients feel better") but whether a given group of patients actually feels better after specific forms of treatment.

How do Gulf War veterans *feel* after they receive treatment from VA? Do they feel better? The same? Worse? As of today, no one knows. There is no data available, only anecdotes. VA has not formally measured health outcomes for Gulf War veterans after they receive care at its medical centers and clinics. With no objective measures of the medical treatment offered, the first part of your question cannot be answered. To answer the question, VA, or an independent group, must first measure health outcomes in Gulf War veterans who seek medical treatment at VA.

In other diseases without a known "cure," the U.S. health care model has evolved an approach over the last 30 years, namely randomized clinical trials of various possibly effective treatments in an attempt to weigh their costs and benefits. While VA conducts outcome studies on Gulf War veterans, it should also conduct randomized controlled trials comparing various treatment methods that have been shown to be effective in treating symptoms commonly reported by Gulf War veterans. These efforts would allow VA to answer your first question with some degree of certainty, while it actively seeks effective treatments for Gulf War illnesses. Once those treatments are identified, VA can then improve the health care it offers to Gulf War veterans.

Sincerely,



Matthew L. Puglisi
Assistant Director
Veterans Affairs and Rehabilitation

¹ Institute of Medicine, *Evaluation of the Department of Defense Persian Gulf Comprehensive Clinical Evaluation Program* (Washington, DC: National Academy Press, 1996). VA and DoD use the same protocol for their clinical programs.

² H.K. Kang, N.A. Dalager, and K.Y. Lee, "Health Surveillance of Persian Gulf War Veterans--A Review of the DVA Persian Gulf Registry Data," unpublished report, Department of Veterans Affairs, March 1996.

³ H.K. Kang, et. al., March 1996

Question for Jeffrey S. Ford
Executive Director
National Gulf War Resource Center
From
The Honorable Luis Gutierrez
Ranking Democratic Member
Subcommittee on Health
House Committee on Veterans Affairs
February 11, 1997

Mr. Ford, you state on page 10 of your testimony that it is time to enlist the support of independent scientists and researchers to get to the bottom of Gulf War syndrome.

Do you believe that it would be worthwhile for Congress to pursue legislation to authorize an independent, broad-based epidemiological study of Gulf War syndrome, the veterans it effects and their families?

The answer to this question is without a doubt, yes. The American College Dictionary defines epidemic as "affecting at the same time a large number of persons in a locality, and spreading from person to person, as a disease not permanently prevalent there." And epidemiology as, "the branch of medicine dealing with epidemic diseases". We know that there are over 100,000 Gulf War veterans that have complained of illnesses connected with their service in the Gulf. This is 1 out of every 7 that were deployed. We know that these illnesses were not present before their deployment and are not statistically consistent with the general population as was shown in the Iowa/CDC Study. And we know from testimony, first hand accounts, and medical evidence that there is a transmissibility factor present, at least concerning close proximity family members. I have seen this in my own work with veterans and would estimate conservatively 10,000 to 20,000 family members to be ill, based on personal interviews combined with known statistical information.

The reasons for research to be conducted independently of the DOD, VA and HHS are as follows. The Presidential Advisory Committee on Persian Gulf War Veterans' Illnesses in their final report found,

"Among the subset of the Gulf War veteran population examined in the ongoing clinical and research programs, many veterans have illnesses likely to be connected to their service in the Gulf. Currently the extent of service connected illness in the population is unknown."(92)

"VA's examination program for spouses and children of Gulf War veterans has little or no value as a research program..."(92)

"DOD and VA have not taken serious steps to encourage their principal investigators to convene and use public advisory committees for it's Gulf War veterans' epidemiological health research."(35)

Therefore, as the DOD, VA and DHHS have not implemented the recommendations of the PAC, and those that are responsible for oversight of these studies are the very individuals within these agencies whose credibility is in question, it is highly unlikely that any credible or useful information will ever be derived from currently planned or on-going studies. It is also unlikely that the results of these studies will be made public without a great deal of pressure. However, it is likely as has been the case in the past, that DOD, VA and DHHS research will be conducted in a manner consistent with the past six years. That is the blatant attempt to disprove the existence of this "syndrome" and to continue to evade the true scope and nature of this problem. The Gulf War veteran community will never accept the findings of any research conducted by these agencies unless these studies are peer-reviewed independent of the government, before, during and after, or conducted solely independent of any Federal agency. Sir, it is not only worthwhile for Congress to pursue this legislation, it is absolutely necessary.

Presidential Advisory Committee
Questions for the Record from the Honorable Lane Evans

1. *How can the executive and legislative branches make better use of the lessons learned from Vietnam?*

The Advisory Committee made several recommendations to improve the government's ability to anticipate and avoid post-conflict health issues. First, the Committee recommended that a Presidential Review Directive (PRD) be issued to instruct the National Science and Technology Council (NSTC) to develop an interagency plan to address health preparedness for and readjustment of veterans and families after future conflicts and peacekeeping missions. The President's Committee of Advisors on Science and Technology and other nongovernmental experts, as appropriate, should be asked to review the plan 12 months after the PRD is issued and again at 18 months to ensure national expertise is brought to bear on these issues. The NSTC's agenda should include the following recommendations for better communication, data, and services, which were developed during the Committee's evaluation of issues related to Gulf War veterans' illnesses.

In the area of better communication, the Committee recommends that DOD and VA immediately develop and implement a comprehensive risk communication plan. This effort should move forward in close cooperation with agencies that have a high degree of public trust and experience with risk communication, such as the Agency for Toxic Substances and Disease Registry and the National Institute for Occupational Safety and Health. The Committee also recommends that FDA solicit timely public and expert comment on any rule that permits waiver of informed consent for use of investigational products in military exigencies. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long-term followup of individuals who receive investigational products; review by an institutional review board outside of DOD; and additional procedures to enhance understanding, oversight, and accountability.

In the area of better data, the Committee identified problems related to missing medical records, the absence of baseline health data, inaccurate records of troop locations, and incomplete data on the health effects of what should have been viewed as reasonably anticipated risks. To help prevent similar problems in the future, we recommend that:

- DOD officials at the highest echelons, including the Joint Chiefs of Staff and the Commanders in Chief, assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data in the field (including classified information, if and when it is needed). DOD and VA should adopt standardized recordkeeping to ensure continuity.
- the Persian Gulf Veterans Coordinating Board and other appropriate departments and agencies be charged to develop a protocol to implement the following recommendation, which was made in the Committee's *Interim Report*: Prior to any deployment, DOD should undertake a thorough health evaluation of a large sample of troops to enable better postdeployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services, including timely postdeployment followup.
- the government develop more accurate and reliable methods of recording troop locations to facilitate post-conflict health research. DOD should make full use of global positioning technologies.
- the government plan for further research on possible long-term health effects of low-level exposure to organophosphorus nerve agents such as sarin, soman, or various pesticides, based on studies of groups with well-characterized exposures, including: a) cases of U.S. workers exposed to organophosphorous pesticides; and b) civilians exposed to the chemical warfare agent sarin during the 1994 and 1995 terrorist attacks in Japan. Additional work should include followup and evaluation of an appropriate subset of any U.S. service personnel who are presumed to be exposed during the Gulf War. The government should begin by consulting with appropriate experts, both governmental and nongovernmental, on organophosphorus nerve agent effects. Studies of human populations with well-characterized exposures will be much more revealing than studies based on animal models, which should be given lower priority.
- the government continue to collect and archive serum samples from U.S. service personnel when feasible.
- research on possible causes and methods of prevention of excess mortality from external causes among veterans receives high priority.
- the government consider methods for routinely sampling military populations regarding reproductive health so that an appropriate baseline exists for evaluating reproductive

outcomes following deployment. In particular, DOD should consult with the National Center for Health Statistics and strongly consider implementing its National Survey of Family Growth and related methodologies for collecting data.

- the entire federal research portfolio place greater emphasis on basic and applied research on the physical effects of stress and on stress-related disorders.

Finally, in the area of better services, the Committee recommends that the government conduct a thorough review of VA's policies concerning reproductive health and seek statutory authority to treat veterans and their families for service-connected problems. When indicated, genetic counseling should be provided—either via VA treatment facilities or referral—to assist veterans and their families who have reproductive concerns stemming from military service. We also recommend that the government continue to intensify efforts to develop stress reduction programs for all troops, with special emphasis on deployed troops.

Presidential Advisory Committee Questions for the Record from the Honorable Luis Gutierrez

1. *Major Knox, the President's Advisory Committee, as you state in your testimony, believes that stress is likely to be an important contributing factor in the range of illnesses currently being reported by Gulf War veterans.*

This may in fact be true.

But, if stress or PTSD is an important factor in causing some PGWS related illnesses, is it your conclusion that Gulf War veterans still should qualify for "priority" health care at VA hospitals?

My fear with this is that if stress becomes the common diagnosis, then our government will divest its obligation to care for our veterans.

We all know, and the President's Committee report describes, the health effects of stress. The health effects of stress are real, then can be debilitating and must be taken as seriously as other causal risk factors.

So, Major Knox, does the Committee conclude that our Gulf War veterans should receive the care and compensation they need, if stress is the most discernible causal factor? I think they should.

Whether a veteran receives a stress-related — or non-stress related — diagnosis is immaterial to qualifying for priority care. The Advisory Committee clearly believes it is the government's obligation to ensure that veterans receive care and compensation for service-connected illnesses.

2. *Major Knox, as I am sure that you and the other members of the Committee are well aware, the Journal of the American Medical Association has published two studies that suggest a link between service in the Gulf War and a variety of Gulf War illnesses.*

The University of Texas Study, conducted by Dr. Haley, reveals that wartime exposure to combinations of chemicals, such as chemical nerve agents, flea collars, and anti-nerve gas pills among some Gulf War veterans were associated with chronic neurotoxic syndromes.

These are important findings.

What will your Committee do in the next nine months to address the new statistical evidence of an association between environmental risk factors and Gulf War syndrome related illnesses? It is obvious that we must examine this statistical evidence as thoroughly as possible.

The Advisory Committee was aware of the general scope of the Texas studies, but the investigators did not release their results until after our report's release, and so the *Final Report* does not present an analysis of these particular studies. However, Dr. Philip J. Landrigan, a member of the Committee, did write an editorial about this work, with which we concur. Dr. Landrigan noted that the studies by Haley and his colleagues "represent further important efforts to classify and categorize symptoms in Gulf War veterans." Still, the studies "have limitations that substantially weaken the authors' strong conclusions." In this regard, Dr. Landrigan noted that the studies are on a single battalion, and hence not generalizable to the broader population of Gulf War veterans. Additionally, the low participation rate (41 percent) raises the issue of selection bias, i.e., those who participated might be significantly different in certain important characteristics even when compared to other individuals who belonged to the battalion but who chose not to join the study. In fact, only 43 percent of nonparticipants who were surveyed reported serious health problems, whereas 70 percent of participants did so. Dr. Landrigan further notes that virtually all information on illnesses is self-reported. Detailed clinical examinations were performed for just 23 symptomatic veterans,

which constitutes less than 4 percent of the battalion, and classic tests to confirm certain neurological damage were made on only 5 veterans. Another significant limitation is that all exposure data were self-reported, and the investigators made no effort to independently or objectively verify exposures. In addition to Dr. Landrigan's review, Committee staff and other experts have noted that among the individuals who participated in neurological testing, neurologists and study investigators were unable to distinguish ill veterans from "well" veterans based on clinical laboratory findings. In other words, the findings were nonspecific and not sufficient to diagnose a syndrome in an individual or any subgroup.

3. *Major Knox, your Committee's report explains that the Department of Defense does not test the health of our soldiers prior to their deployment in an active duty field of operations.*

I believe that in order for our government to prevent future post-Gulf War situations, we must think in the long-term by rigorously testing and recording data on our soldiers prior to their service overseas. If Congress must act to ensure that this is accomplished, then we should do so immediately.

As the new ranking Democrat on the Subcommittee on Health, I feel strongly that Congress must work on legislative means to see that our soldiers never return from war with unexplainable illnesses again.

Major Knox or Dr. Russell, what do you believe Congress can do to prevent future Gulf War crises?

Please see the response to the question submitted by Representative Evans.



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